OLYMPUS®

INSTRUCTIONS

EVIS EXERA II

EVIS EXERA II ULTRASOUND GASTROVIDEOSCOPE

OLYMPUS GF TYPE UCT180

CAUTION : Balloons Used with This Product Contain Natural Rubber Latex, Which May Cause Allergic Reactions.

USA: CAUTION: Federal law restricts this device to sale by or on the order of a physician.	CE 0197

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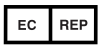
Symbols

The meaning(s) of the symbol(s) shown on the package, the back cover of this instruction manual and/or this instrument are as follows:

	Refer to instructions.
	Caution
	TYPE BF applied part
	Serial number
IPX7	Ingress protection rating (except for connectors)
	Lock the ultrasound connector
	Release the ultrasound connector
	Ultrasonic endoscope
	Single use only
	Do not resterilize
	Use by (expiration date)
	Sterilized using ethylene oxide
	Sterilization lot number
	Lot number

	Nonsterile
	Keep away from sunlight
	Keep dry
	Do not use if package is damaged
	Contains or Presence of Natural Rubber Latex
	Date of manufacture
	Manufacturer
	Authorized representative in the European Community

Important Information — Please Read Before Use

Intended use

This instrument has been designed to be used with an Olympus universal endoscopic ultrasound center or a diagnostic ultrasound system (ALOKA CO., LTD), video system center, light source, documentation equipment, monitor, EndoTherapy accessories and other ancillary equipment.

This instrument is designed for endoscopic real-time ultrasound imaging, ultrasound guided needle aspiration and other endoscopic procedures within the upper gastrointestinal tract and surrounding organs.
Do not use this instrument for any purpose other than its intended use.

Applicability of endoscopy and endoscopic treatment

If there is an official standard on the applicability of endoscopy and endoscopic treatment that is defined by the hospital's administration or other official institutions such as academic societies on endoscopy, follow that standard.
Before starting endoscopy and endoscopic treatment, thoroughly evaluate its properties, purposes, effects, and possible risks (their nature, extent, and probability). Perform endoscopy and endoscopic treatment only when its potential benefits are greater than its risks.
Fully explain to the patient the potential benefits and risks of the endoscopy and endoscopic treatment as well as any examination/treatment methods that can be performed in its place, and perform the endoscopy and endoscopic treatment only after obtaining the consent of the patient.
Even after starting the endoscopy and endoscopic treatment, continue to evaluate the potential benefits and risks, and immediately stop the endoscopy/treatment and take proper measures if the risks to the patient become greater than the potential benefits.

Instruction manual

This instruction manual contains essential information for using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment that will be used during the procedure. Then use the equipment as instructed.
Keep this and all related instruction manuals in a safe and accessible location. If you have any questions or comments about any information in this manual, please contact Olympus.

❍ Terms used in this manual

NBI (Narrow Band Imaging) observation mode:

This is an observation mode using narrow band observation light.

Normal light observation (or WLI (White Light Imaging) observation mode):

This is an observation mode using the standard white light illumination.

Elastography:

Mode for displaying the relative elasticity information of a tissue using color images.
For more details, refer to the instruction manual for the ultrasound instrument for which elastography is available.

User qualifications

If there are official standards for user qualifications for performing endoscopy and endoscopic treatment that are defined by the hospital's medical administrators or other official institutions, such as academic societies on endoscopy, follow those standards. If there are no official qualification standards, the operator of this instrument must be a physician approved by the medical safety manager of the hospital or person in charge of the department (department of internal medicine, etc.).
The physician should be capable of safely performing the planned endoscopy and endoscopic treatment following guidelines set by the academic societies on endoscopy, etc., and considering the difficulty of endoscopy and endoscopic treatment. This manual does not explain or discuss endoscopic procedures.

Instrument compatibility

Refer to the “System chart” in the Appendix to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient or operator injury and/or equipment damage.

This instrument complies with EMC standard for medical electrical equipment, edition 3 (IEC 60601-1-2: 2007). However, when connected with an instrument that complies with EMC standard for medical electrical equipment, edition 1 (IEC 60601-1-2: 1993), the whole system complies with edition 1.

Reprocessing before the first use/reprocessing and storage after use

This instrument was not cleaned, disinfected, or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in Chapter 7, “Cleaning, Disinfection, and Sterilization Procedures”.

After using this instrument, reprocess and store it according to the instructions given in the endoscope’s companion reprocessing manual. Improper and/or incomplete reprocessing or storage can present an infection control risk, cause equipment damage, or reduce performance.
The balloons are disposable, and are intended for a single use only; a new one must be used for each patient. Do not attempt to reuse or resterilize a balloon.

Spare equipment

Be sure to prepare another endoscope to avoid interruption of the examination due to equipment failure or malfunction.

Maintenance management

The probability of failure of the endoscope and ancillary equipment increases as the number of procedures performed and/or the total operating hours increase. In addition to the inspection before each procedure, the person in charge of medical equipment maintenance in each hospital should inspect the items specified in this manual periodically. An endoscope with an observed irregularity should not be used, but should be inspected by following Section 10.1, “Troubleshooting guide” on page 154. If the irregularity is still observed after inspection, contact Olympus.

Prohibition of improper repair and modification

This instrument does not contain any user-serviceable parts. Do not disassemble, modify, or attempt to repair it; patient or operator injury and/or equipment damage can result. Equipment that has been disassembled, repaired, altered, changed, or modified by persons other than Olympus’ own authorized service personnel is excluded from Olympus’ limited warranty and is not warranted by Olympus in any manner.

Signal words

The following signal words are used throughout this manual:

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

NOTE

Indicates additional helpful information.

Warnings and cautions

Follow the warnings and cautions given below when handling this instrument. This information is to be supplemented by the warnings and cautions given in each chapter.

WARNING

- After using this instrument, reprocess and store it according to the instructions given in Chapter 7, “Cleaning, Disinfection, and Sterilization Procedures”. Using improperly or incompletely reprocessed or stored instruments may cause patient cross-contamination and/or infection.
- Before endoscopy, remove any metallic objects (watch, glasses, necklace, etc.) from the patient. Performing high-frequency cauterization treatment while the patient is wearing metallic objects may cause burns on the patient in areas around the metallic objects.
- Move the elevator control lever slowly in the opposite direction of the “◀U” direction until it stops and visually confirm that the portion of the elevator wire extending from the distal end of the insertion section is not broken or bent. If the elevator wire is broken or bent, patient injury, bleeding, and/or perforation could result.
- Do not strike, hit, or drop the endoscope’s distal end, insertion tube, bending section, control section, universal cord, or endoscope connector. Also, do not bend, pull, or twist the endoscope’s distal end, insertion tube, bending section, control section, universal cord, or endoscope connector with excessive force. The endoscope may be damaged and could cause patient injury, burns, bleeding, and/or perforations. It could also cause parts of the endoscope to fall off inside the patient.
- Never perform angulation control forcibly or abruptly. Never forcefully pull, twist, or rotate the angulated bending section. Patient injury, bleeding, and/or perforation may result. It may also become impossible to straighten the bending section during an examination.
- Never insert or withdraw the endoscope’s insertion section while the bending section is locked in position. Patient injury, bleeding, and/or perforation may result.

- Never operate the bending section, feed air, perform suction, insert or withdraw the endoscope's insertion section, or use EndoTherapy accessories without viewing the endoscopic image. Patient injury, bleeding, and/or perforation may result.
- Never operate the bending section, feed air, perform suction, insert or withdraw the endoscope's insertion section, or use EndoTherapy accessories while the image is frozen. Patient injury, bleeding, and/or perforation may result.
- Never insert or withdraw the insertion section abruptly or with excessive force. Patient injury, bleeding, and/or perforation may result.
- Do not touch the light guide of the endoscope connector immediately after removing it from the light source because it is extremely hot. Operator or patient burns can result.
- That before each use or after a change of viewing modes/settings, check to ensure the view observed through the endoscope provides a live image (rather than a stored one) and has the correct image orientation. Patient injury, bleeding, and/or perforation could result.
- When the endoscopic image does not appear on the monitor, the CCD may have been damaged. Turn the video system center OFF immediately. Continued power supply in such a case will cause the distal end to become hot and could cause operator and/or patient burns.
- Turn ON the diagnostic ultrasound system only when the ultrasonic cable is connected to both the diagnostic ultrasound system and the ultrasonic cable connector on the endoscope. In particular, confirm that the diagnostic ultrasound system is OFF before connecting or disconnecting the ultrasonic cable from the ultrasonic cable connector on the endoscope. Operator injury may result and/or equipment damage may result.
- Do not rely on the NBI observation mode alone for primary detection of lesions or to make a decision regarding any potential diagnostic or therapeutic intervention.
- Never withdraw the endoscope while the balloon is still inflated. Otherwise, the balloon may burst or detach from the distal end of the endoscope. If the balloon cannot be deflated, insert the channel cleaning brush (BW-7L) into the balloon channel. Using slow, short strokes, carefully feed the brush to remove debris.

- When withdrawing the endoscope, make sure that the balloon is completely deflated, using the ultrasound image and endoscopic field of view. Withdrawing the endoscope while the balloon is inflated could result in patient injury.
- If it is difficult to insert the endoscope, do not forcibly insert the endoscope; stop the endoscopy. Forcible insertion can result in patient injury, bleeding, and/or perforation.
- If any irregularity in the ultrasound image is observed, turn the ultrasound center OFF immediately. Continued ultrasound radiation will cause the distal end to become hot and could cause operator and/or patient burns.
- Elastography[*1] uses the pulsation of a living body. Intentional pressurization is not necessary. Compression onto the tissue by operating the bending section, inserting or withdrawing the endoscope may cause tissue damage, bleeding or perforation.

  ∗1 Elastography is not available with the diagnostic ultrasound system (Hitachi Aloka Medical, Ltd.) in Canada.

CAUTION

- After using the endoscope reprocess it according to the instructions given in Chapter 7, “Cleaning, Disinfection, and Sterilization Procedures”. Using improperly or incompletely reprocessed, the endoscope’s distal end damage may result.
- Do not pull the universal cord during an examination. The endoscope connector will be pulled out from the output socket of the light source and the endoscopic image will not be visible.
- Do not coil the insertion tube or universal cord with a diameter of less than 12 cm. Equipment damage can result.
- Do not attempt to bend the endoscope’s insertion section with excessive force. Otherwise, the insertion section may be damaged.
- Do not touch the electrical contacts inside the videoscope cable connector. CCD damage may result.
- Do not apply shock to the distal end of the insertion section, particularly the ultrasound transducer and the objective lens surface at the distal end. Visual abnormalities may result.
- Do not hold the ultrasonic transducer when holding the insertion tube. The ultrasonic transducer damage can result and/or the ultrasonic image will be abnormal.

- Do not twist or bend the bending section with your hands. Equipment damage may result.
- Do not squeeze the bending section forcefully. The covering of the bending section may stretch or break and cause water leaks.
- Turn the video system center ON only when the videoscope cable is connected to both the video system center and the videoscope cable connector on the endoscope. In particular, confirm that the video system center is OFF before connecting or disconnecting the videoscope cable from the electrical connector on the endoscope. Failure to do so can result in equipment damage, including destruction of the CCD.
- The endoscope's remote switches cannot be removed from the control section. Pressing, pulling, or twisting them with excessive force can break the switches and/or cause water leaks.
- If remote switch 1 does not return to the OFF position after being pressed strongly from the side, gently pull the switch upwards to return it to the OFF position.
- Do not hit or bend the electrical contacts on the endoscope connector. The connection to the light source may be impaired and faulty contact can result.
- Do not touch the electrical contacts in the ultrasonic cable connector. Equipment damage can result.
- Do not pull, twist or tightly coil the ultrasonic cable. Noise can develop in the ultrasound image.
- Electromagnetic interference may occur on this instrument near equipment marked with the following symbol or other portable and mobile RF (radio frequency) communications equipment such as cellular phones. If electromagnetic interference occurs, mitigation measures may be necessary, such as reorienting or relocating this instrument, or shielding the location.

- To check the electromagnetic interference from other equipment (any equipment other than this instrument or the components that constitute this system), the system should be observed to verify its normal operation in the configuration in which it will be used.

- To prevent unnecessary patient exposure to ultrasound radiation, follow the ‘as-low-as-reasonably achievable’ (ALARA) principle when using ultrasound equipment. Freeze the image whenever you are not actively viewing the “live” ultrasound image. When the equipment is in the FREEZE mode, no ultrasound energy is emitted.

NOTE

- It is highly recommended that a backup ultrasonic cable be available to continue clinical procedures in case of a malfunction.
- This endoscope contains a memory chip that stores information about the endoscope and communicates this information to the video system center CV-160 and CV-180.

Examples of inappropriate handling

Details on clinical endoscopic technique are the responsibility of trained specialists. Patient safety in endoscopic examinations and endoscopic treatment can be ensured through appropriate handling by the physician and the medical facility. Examples of inappropriate handling are described below.

- Over-insufflating the lumen may cause patient pain, injury, bleeding, and/or perforation.
- Applying suction with the distal end in prolonged contact with the mucosal surface, with higher suction pressure than required, or with prolonged suction time may cause bleeding and/or lesions.
- The endoscope has not been designed for use in retroflexed observation in parts of the body other than the stomach. Performing retroflexed observation in a narrow lumen may make it impossible to straighten the angle of the bending section and/or withdraw the endoscope from the patient. Retroflexed observation in parts of the body other than the stomach should be performed only when the usefulness of doing so is determined to be greater than the risk that is posed to the patient.
- Inserting, withdrawing, and using EndoTherapy accessories without a clear endoscopic image may cause patient injury, burns, bleeding, and/or perforation.
- Inserting or withdrawing the endoscope, feeding air, applying suction, or operating the bending section without a clear endoscopic image may cause patient injury, bleeding, and/or perforation.

- For reasons described below, do not rely on the NBI*1 observation mode alone for primary detection of lesions or to make a decision regarding any potential diagnostic or therapeutic intervention.
  - NBI has not been demonstrated to increase the yield or sensitivity of finding any specific mucosal lesion including colonic polyps or Barrett's esophagus.
  - NBI has not been demonstrated to aid in differentiating establishing the presence or absence of dysplasia or neoplastic changes within mucosa or mucosal lesions.

*1 NBI stands for Narrow Band Imaging. For more details, refer to the instruction manual for the video system center CV-180.

Natural rubber latex medical alert

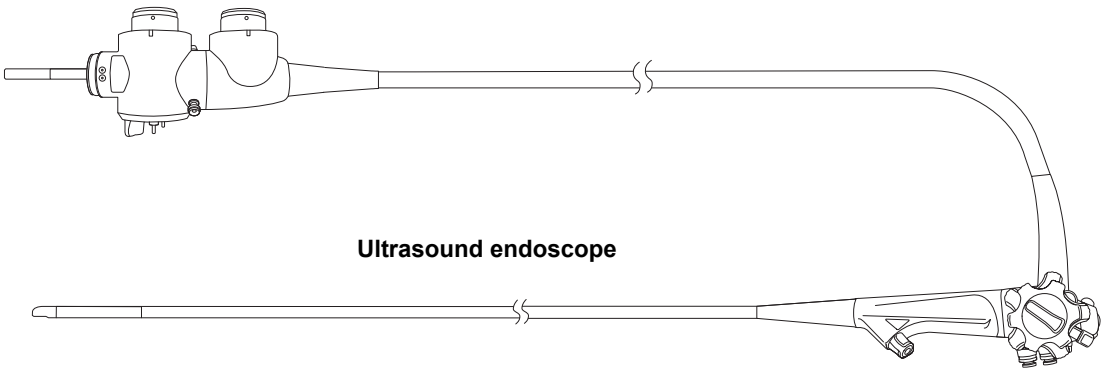
CAUTION

Balloons used with this instrument contain natural rubber latex that may cause allergic reactions.
Do not use the balloon on a latex-sensitive patient. Instead, perform the procedure using "The sterile deaerated water immersion method" described in Section 4.2, "Observation of the ultrasound image" on page 64, in Chapter 4, "Operation".

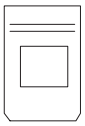
Chapter 1 Checking the Package Contents

1.1 Standard components

Match all items in the package with the components shown below. Inspect each item for damage. If the instrument is damaged, a component is missing, or you have any questions, do not use the instrument; immediately contact Olympus. This instrument was not disinfected or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in Chapter 7, “Cleaning, Disinfection, and Sterilization Procedures”.

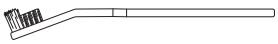


Ultrasound endoscope

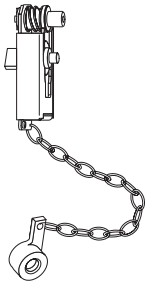


Balloon 3 for the USA (MAJ-249 sterile, 20 pcs.)
Balloon for countries other than the USA (MAJ-213, nonsterile, 20 pcs.)

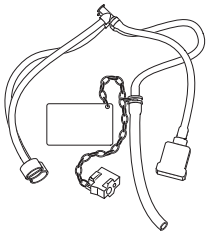
Mouthpiece (MB-142, 2 pcs.)



Cleaning brush (MAJ-1534)



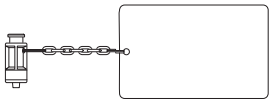
Channel plug (MAJ-621)



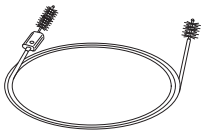
Injection tube (MH-946)

Single use channel cleaning brush for the USA (BW-201T, 3 pcs.*1)
Channel cleaning brush for countries other than the USA (BW-20T, 1 pcs.)

Channel cleaning brush (BW-7L, 2 pcs.*1)
Single use single-ended cleaning brush (BW-400L, 3 pcs.*1)



Cleaning adapter for instrument channel port (MAJ-350)

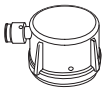


Single use combination cleaning brush (BW-412T, 3 pcs.*1)

Single use channel-opening cleaning brush for the USA (MAJ-1339, 3 pcs.*1)
Channel-opening cleaning brush for countries other than the USA (MH-507, 1 pcs.)

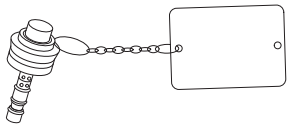
Biopsy valve (MAJ-853, nonsterile, 10 pcs.)

Balloon applicator (MAJ-675)

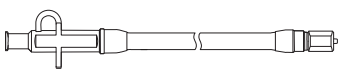


Water-resistant cap (MH-553, 2 pcs.)

Suction cleaning adapter (MH-856)

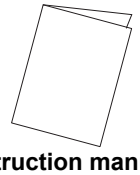


Air/water channel cleaning adapter (MAJ-629)



Washing tube (MH-974)

Chain for water-resistant cap (MAJ-1739)



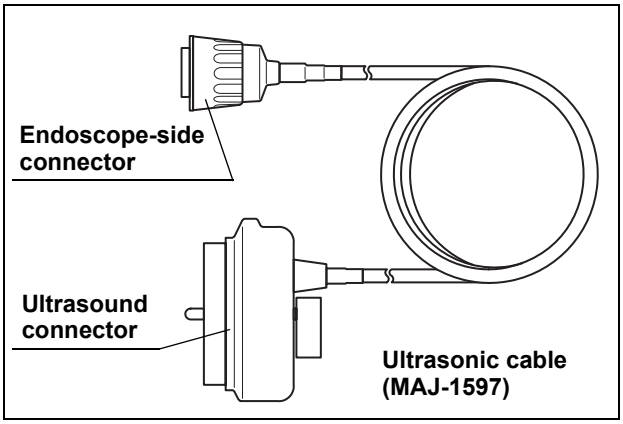
Instruction manual

*1 These products may not be available in some areas.

1.2 Ultrasonic cable

The ultrasonic cable (MAJ-1597) is necessary to use this endoscope (GF-UCT180), but it must be purchased separately (optional) from Olympus.

- **For Olympus universal endoscopic ultrasound center EU-ME1 and the diagnostic ultrasound system (ALOKA CO., LTD)**



1.3 Optional components

The item listed below is optional for countries other than the USA, and may be purchased from Olympus.

Balloon 3

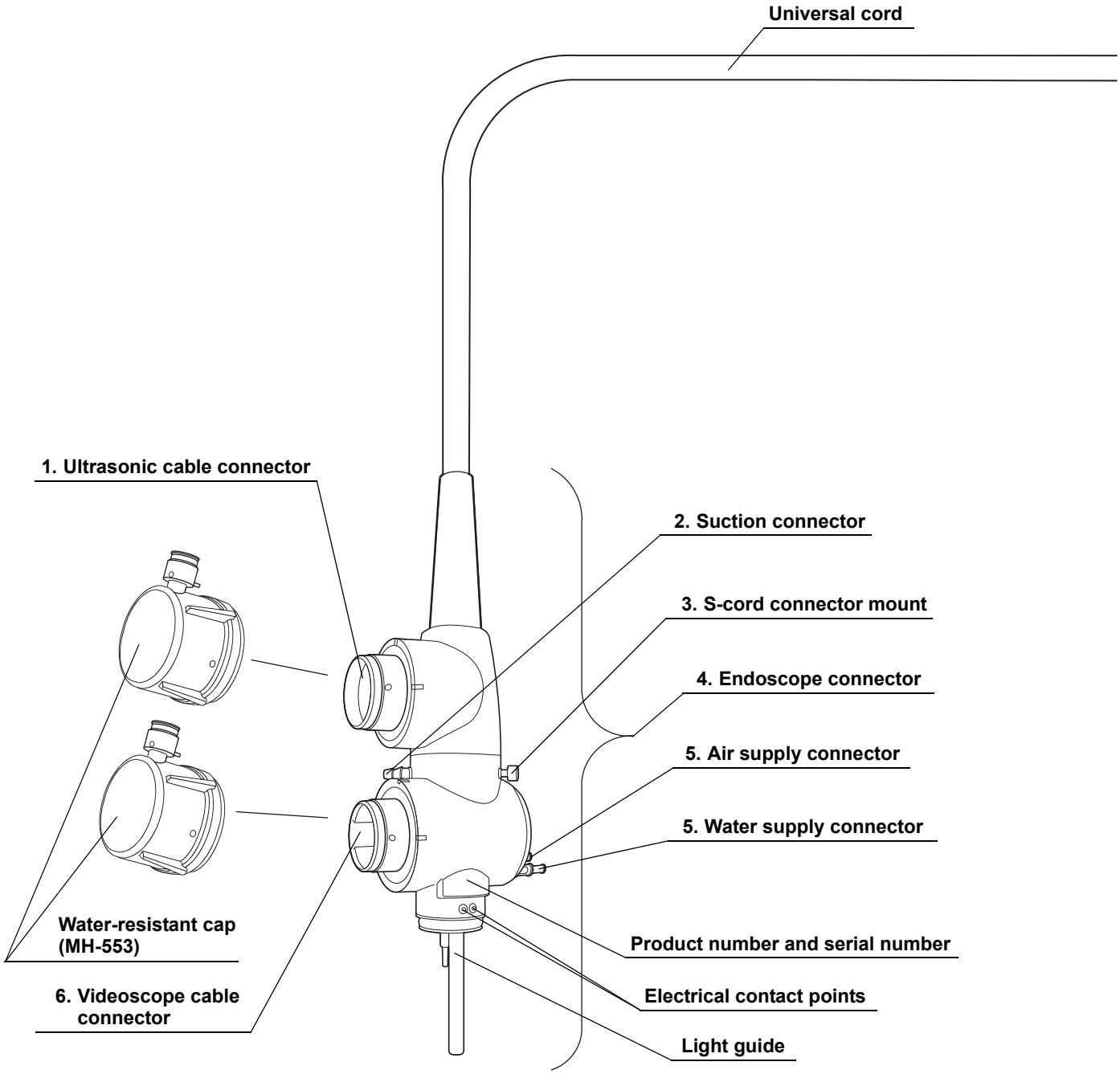
Balloon 3 is shipped sterile in sets of 20 pieces, enclosed in a resealable package. The correct model to be used with this endoscope is listed in Table 1.1 below.

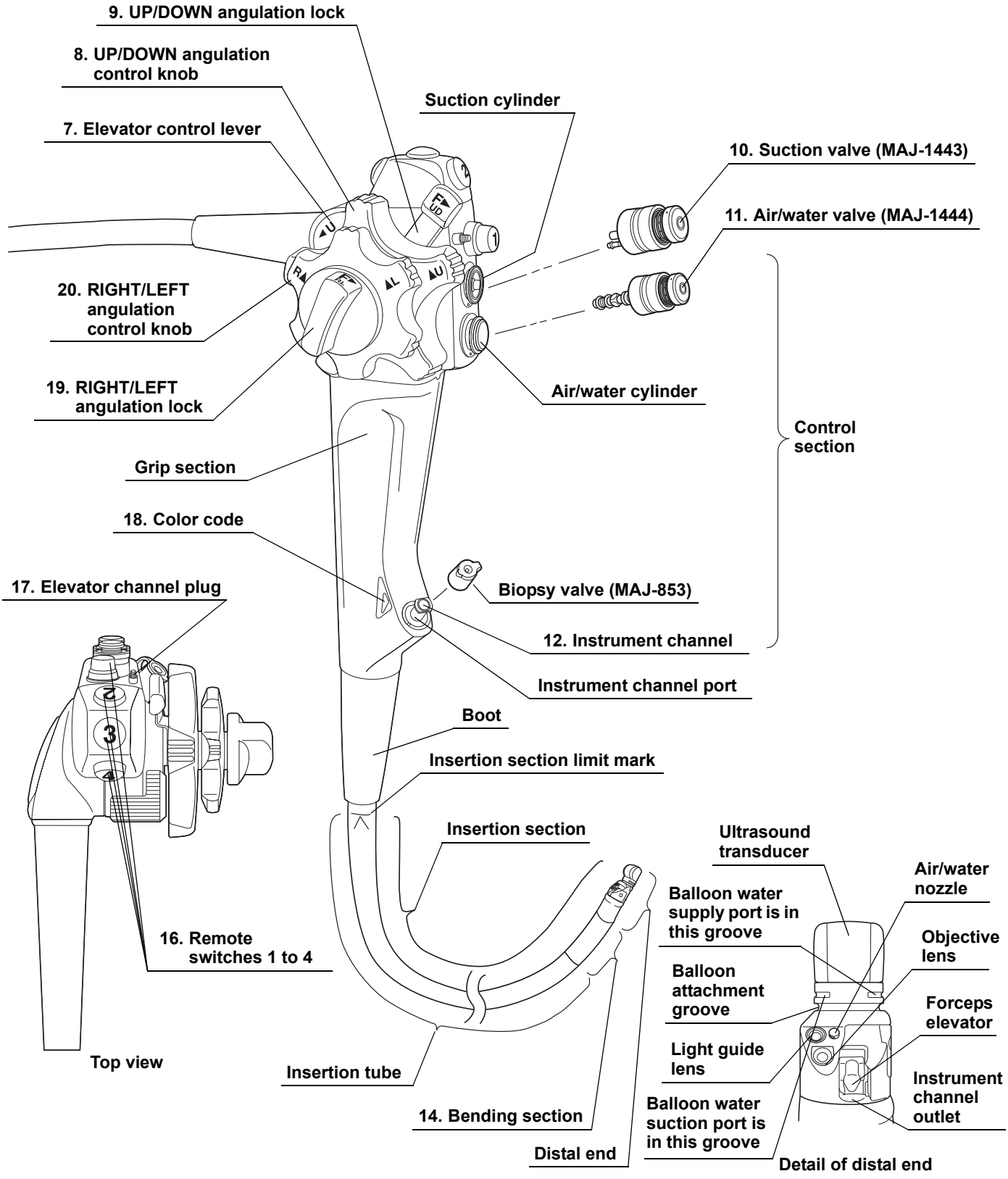
Endoscope	Balloon 3
GF-UCT180	MAJ-249

Table 1.1

Chapter 2 Instrument Nomenclature and Specifications

2.1 Nomenclature




9. UP/DOWN angulation lock
8. UP/DOWN angulation control knob
Suction cylinder
7. Elevator control lever
10. Suction valve (MAJ-1443)
11. Air/water valve (MAJ-1444)
20. RIGHT/LEFT angulation control knob
Air/water cylinder
19. RIGHT/LEFT angulation lock
Control section
Grip section
18. Color code
17. Elevator channel plug
Biopsy valve (MAJ-853)
12. Instrument channel
Instrument channel port
Boot
Insertion section limit mark
Insertion section
Ultrasound transducer
Air/water nozzle
Balloon water supply port is in this groove
Objective lens
Balloon attachment groove
Forceps elevator
Light guide lens
Instrument channel outlet
16. Remote switches 1 to 4
Top view
Insertion tube
14. Bending section
Balloon water suction port is in this groove
Distal end
Detail of distal end

2.2 Endoscope functions

1. **Ultrasonic cable connector**
   Connects the ultrasonic cable of the ultrasound diagnostic equipment to the endoscope.
2. **Suction connector**
   Connects the endoscope to the suction tube of the suction pump.
3. **S-cord connector mount**
   Connects the endoscope with the Olympus electrosurgical unit via the S-cord. The S-cord conducts leakage current from the endoscope to the electrosurgical unit. To connect the S-cord, refer to the instruction manual for the electrosurgical unit. Connect the fitting part of the chain for water-resistant cap to this mount, as required (see Section 2.4, “Attaching the chain for water-resistant cap (MAJ-1739)” on page 25).
4. **Endoscope connector**
   Connects the endoscope to the output socket of the light source and transmits light from the light source to the endoscope.
5. **Water supply connector and air supply connector**
   Connects the endoscope to the water container via the water container tube to supply water to the distal end of the endoscope.
6. **Videoscope cable connector**
   Connects the endoscope to the video system center via the videoscope cable. The endoscope contains a memory chip that stores information about the endoscope and communicates this information to the video system center CV-160, CV-180. For more details, refer to the instruction manual for the CV-160, CV-180.
7. **Elevator control lever**
   When this lever is moved in the “◀U” direction, the forceps elevator is raised; when the lever is moved in the opposite direction, the forceps elevator is lowered.
8. **UP/DOWN angulation control knob**
   When this knob is turned in the “▲U” direction, the bending section moves UP; when the knob is turned in the “D▲” direction, the bending section moves DOWN.
9. **UP/DOWN angulation lock**
   Moving this lock in the “F▶” direction frees angulation. Moving the lock in the opposite direction locks the bending section at any desired position.

10. **Suction valve (MAJ-1443)**

The suction valve is depressed to the first stage to activate suction. The valve is also used to remove any fluid or debris adhering to the objective lens.

The suction valve is depressed completely to activate suction of sterile water from the balloon through the balloon channel.

11. **Air/water valve (MAJ-1444)**

The hole in the air/water valve is covered to insufflate air and the valve is depressed to the first stage to feed water for lens washing. It also can be used to feed air to remove any fluid or debris adhering to the objective lens. The valve is depressed completely to fill the balloon with sterile water through the balloon channel.

12. **Instrument channel**

The instrument channel functions as:

- channel for the insertion of EndoTherapy accessories
- suction channel
- Fluid feed channel (from a syringe via the biopsy valve)

13. **Insertion section limit mark**

This mark shows the maximum point to which the endoscope may be inserted into the patient's body.

14. **Bending section**

This section moves the distal end of the endoscope when the UP/DOWN and RIGHT/LEFT angulation control knobs are operated.

15. **Forceps elevator**

The elevator moves EndoTherapy accessories when the elevator control lever is operated.

16. **Remote switches 1 to 4**

The functions of remote switches 1 to 4 can be selected on the video system center. Refer to the instruction manual for the video system center when setting these functions.

17. **Elevator channel plug**

This plug is used for connection of the washing tube to clean and disinfect the elevator channel.

18. **Color code (orange)**

This code is used to quickly determine the compatibility of EndoTherapy accessories. The endoscope can be used with EndoTherapy accessories that have the same color code. For more information on combining the endoscope with particular EndoTherapy accessories, refer to the "System chart" in the Appendix and the instruction manuals for the compatible accessories.

19. **RIGHT/LEFT angulation lock**
Turning this lock in the "F▶" direction frees angulation. Turning the lock in the opposite direction locks the bending section at any desired position.

20. **RIGHT/LEFT angulation control knob**
When this knob is turned in the "R▲" direction, the bending section moves RIGHT; when the knob is turned in the "▲L" direction, the bending section moves LEFT.

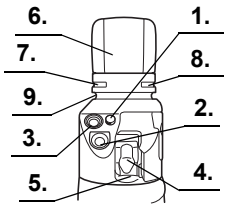
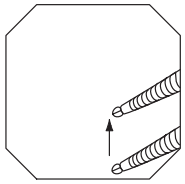
2.3 Specifications

Environment

Operating environment	**Ambient temperature**	10 – 40°C (50 – 104°F)
	Relative humidity	30 – 85%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)
Transportation and storage environment	**Ambient temperature**	–47 to 70°C (–52.6 to 158°F)
	Relative humidity	10 – 95%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)

Specifications

❍ Endoscope functions

Model		GF-UCT180
Optical system	**Field of view**	100°
	Direction of view	55° forward oblique
	Depth of field	3 – 100 mm
Insertion tube	**Distal end outer diameter**	ø 14.6 mm
	Distal end enlarged	1. Air/water nozzle 2. Objective lens 3. Light guide lens 4. Forceps elevator 5. Instrument channel outlet 6. Ultrasonic transducer 7. Balloon water supply port 8. Balloon suction port 9. Balloon attachment groove 
	Insertion tube outer diameter	ø 12.6 mm
	Working length	1250 mm
Instrument channel	**Channel inner diameter**	ø 3.7 mm
	Minimum visible distance	6 mm from the objective lens
	Direction from which EndoTherapy accessories enter and exit the endoscopic image	
Airflow rate		20 cm^3/s Note: Standard when CLV-180 (high air pressure) is used.

Bending section	**Angulation range**	UP 130°, DOWN 90°, RIGHT 90°, LEFT 90°
Total length		1555 mm
NBI observation mode[*1]		Available

*1 For more details, refer to the instruction manual for the CV-180.

❍ Ultrasound function with ALOKA diagnostic ultrasound system SSD-α10/ProSound α7[*1]/ProSound F75[*1]

Operation mode	B-mode, M-mode, D-mode, Bflow mode, Powerflow mode
Scanning method	Electronic curved linear array
Scanning direction	Parallel to the insertion direction
Receiving frequency	5, 6, 7.5, 10 MHz (SSD-α10/ProSound F75[*1]) 4, 6.67, 10, 13.3 MHz (ProSound α7)[*1]
Scanning range	180°
Contacting method	Balloon method, Direct contact method
Transducer surface max. temperature	43°C >

*1 These products may not be available in some areas.

❍ Ultrasound function with Olympus universal endoscopic ultrasound center EU-ME1

Operation mode	B mode, color flow mode, power flow mode
Scanning method	Electronic curved linear array
Scanning direction	Parallel to the insertion direction
Receiving frequency	5, 6, 7.5, 10, 12 MHz
Scanning range	180°
Contacting method	Balloon method, Direct contact method
Transducer surface max. temperature	43°C >

General safety standard for medical electrical equipment	**IEC 60601-1: 2005**	Whole of this instrument is possible to contact live bodies of operators or patients.
Medical Devices Directive	CE 0197	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class II a
EMC	**Applied standards; IEC 60601-1-2: 2007 IEC 60601-2-37: 2007**	This instrument complies with the standards listed in the left column. CISPR 11 of emission: Group 1, Class B This instrument complies with the EMC standard for medical electrical equipment, edition 3 (IEC 60601-1-2: 2007). However, when connecting to an instrument that complies with the EMC standard for medical electrical equipment, edition 1 (IEC 60601-1-2: 1993), the whole system complies with edition 1.
Year of manufacture	**1912345** ↑	The last digit of the year of manufacture is given in the second digit of the serial number.
Degree of protection against electric shock		TYPE BF applied part
Ingress protection rating	**IPX7**	This instrument complies with the standards for medical electrical equipment: IEC 60601-1: 2005 IEC 60601-2-37: 2007.

2.4 Attaching the chain for water-resistant cap (MAJ-1739)

CAUTION

- Do not lift the endoscope by the chain for water-resistant cap. Doing so may result in the fitting part of the chain detaching from the S-cord connector mount, causing the endoscope to fall. This could cause operator or patient injury and/or equipment damage.
- Connect the fitting part only to the S-cord connector mount. Connecting the fitting part to the suction connector may impair the connection of the suction tube to the suction connector. It may also cause the suction tube to become disconnected from the endoscope and allow patient debris to spray.
- The chain for water-resistant cap and water-resistant cap itself cannot be ultrasonically cleaned; doing so could damage them. The water-resistant cap with the chain can only be ultrasonically cleaned if connected to endoscopes that are being cleaned in an endoscope reprocessor (such as OER[*1], OER-A[*1]) with an ultrasonic cleaning phase.

  *1 These products may not be available in some areas.

- Connecting the fitting part to the suction connector may impair the connection of the suction tube to the suction connector. It may also cause the suction tube to become disconnected from the endoscope and allow patient debris to spray.
- When attaching the water-resistant cap to the connector of the endoscope, do not pinch the chain for water-resistant cap between the connector of the endoscope and the water-resistant cap. Otherwise, equipment damage may result.
- The chain for water-resistant cap and water-resistant cap cannot be steam sterilized (autoclaved); doing so can damage them severely.

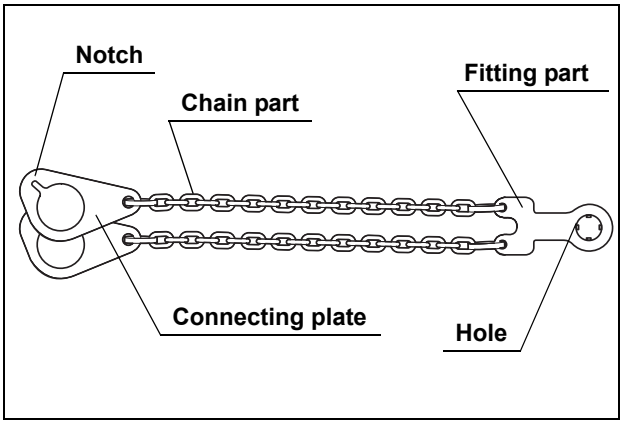


Figure 2.1

NOTE

To ensure that you do not forget to attach the water-resistant cap, it is recommended that you connect the chain for water-resistant cap to the endoscope's S-cord connector mount.

1. Confirm that the chain for water-resistant cap is free from cracks, flaws, wear, deformation, or other damages (see Figure 2.1).
2. Align the notch on the connecting plate with the pin on the venting connector of the water-resistant cap (MH-553, see Figure 2.2).
3. Place the connecting plate over the venting connector (see Figure 2.2).
4. Confirm that the connecting plate is securely attached to the foot of the venting connector and can be smoothly rotated.
5. Place the hole on the fitting part over the endoscope's S-cord connector mount.

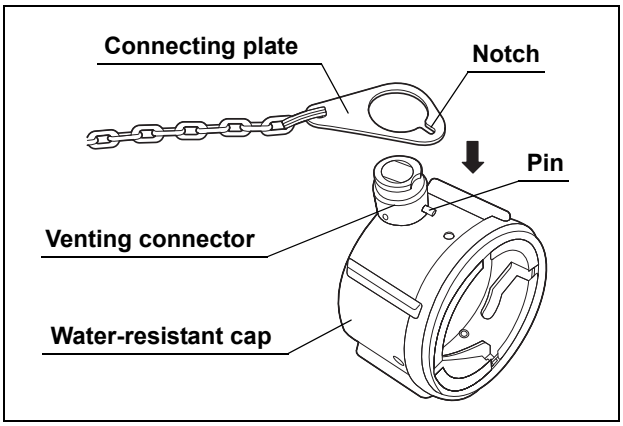


Figure 2.2

NOTE

The instructions on the remaining pages of this manual are given under the assumption that the chain for water-resistant cap is detached from the endoscope.

Chapter 3 Preparation and Inspection

Before each procedure, prepare and inspect this instrument as instructed below. Inspect other equipment to be used with this instrument as described in their respective instruction manuals. If this instrument malfunctions, do not use it. Return it to Olympus for repair as described in Section 10.3, “Returning the endoscope for repair” on page 161. If any irregularities are suspected after inspection, follow the instructions given in Chapter 10, “Troubleshooting”.

WARNING

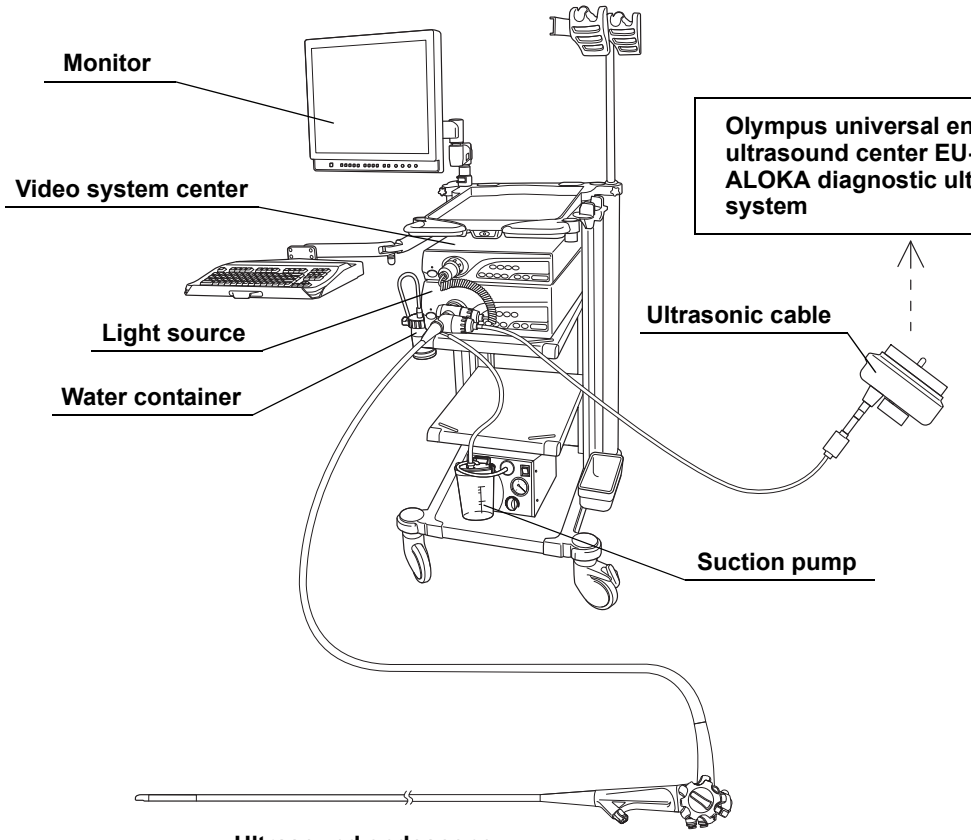
- This instrument was not cleaned, disinfected, or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in Chapter 7, “Cleaning, Disinfection, and Sterilization Procedures”.
- Using an instrument that is not functioning properly may compromise patient or operator safety and may result in more severe equipment damage.

CAUTION

Do not pull the universal cord or the ultrasonic cable with excessive force when the endoscope is connected to the other equipment. Doing so could cause equipment damage.

3.1 Preparation of the equipment

Prepare the equipment shown in Figure 3.1 (for compatibility, see the “System chart” in the Appendix) and personal protective equipment, such as eyewear, face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed. Refer to the respective instruction manuals for each piece of equipment.



- **Paper towels**
- **Trays**
- **Lint-free cloths**
- **Personal protective equipment**
- **3-way stopcock**
- **Syringe**
- **Extension tube**
- **Sterile deaerated water**
- **Medical-grade, water-soluble lubricant**

Figure 3.1

3.2 Inspection of the endoscope

Clean and disinfect or sterilize the endoscope as described in Chapter 7, “Cleaning, Disinfection, and Sterilization Procedures” and Chapter 8, “Cleaning and Disinfection Equipment” of this manual. Then remove the water-resistant cap from the endoscope connector.

Inspection of the endoscope

1. Inspect the control section and the endoscope connector for excessive scratching, deformation, loose parts, or other irregularities.
2. Inspect the boot and the insertion section near the boot for bends, twists, or other irregularities.
3. Inspect the external surface of the entire insertion section including the bending section and the distal end for dents, bulges, swelling, scratches, holes, sagging, transformation, bends, adhesion of foreign bodies, missing parts, protruding objects, or other irregularities.
4. Gently holding the insertion section with one hand, carefully run your other hand back and forth over the entire length of the insertion section (see Figure 3.2). Confirm that no objects or metallic wire protrude from the insertion section. Also, confirm that the insertion tube is not abnormally rigid.

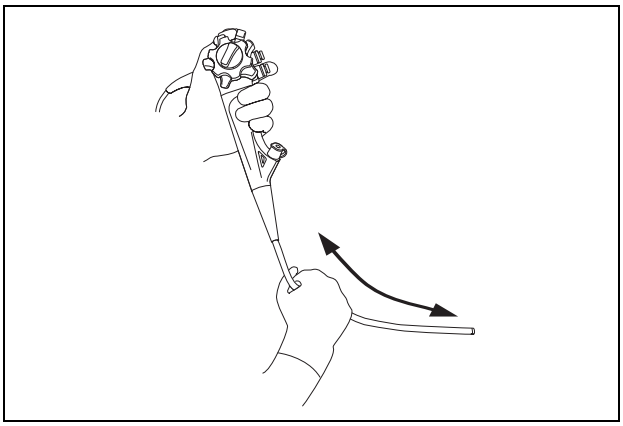


Figure 3.2

5. Using both hands, bend the insertion tube of the endoscope into a semicircle. Then, moving your hands as shown by the arrows in Figure 3.3, confirm that the entire insertion tube can be smoothly bent to form a semicircle and that the insertion tube is pliable.

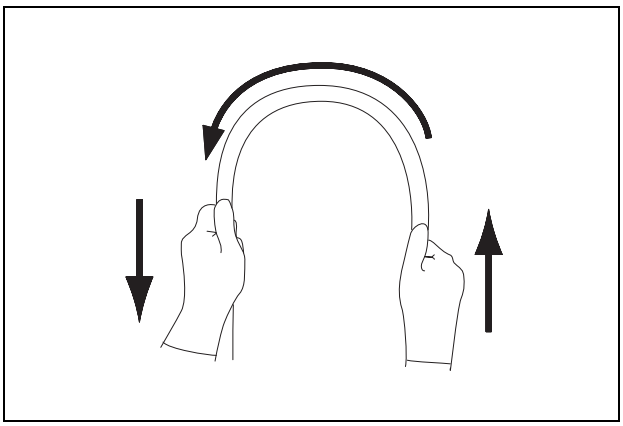


Figure 3.3

6. Gently hold the midpoint of the bending section and a point 20 cm from the distal end. Push and pull gently to confirm that the junction between the bending section and the insertion tube is not loose.
7. Inspect the objective lens and light guide lens at the distal end of the endoscope's insertion section for scratches, cracks, stains, or other irregularities.
8. Inspect the air/water nozzle at the distal end of the endoscope's insertion section for abnormal swelling, bulges, dents, or other irregularities.
9. Inspect the ultrasound transducer surface at the distal end of the endoscope's insertion tube for scratching, cracks, bulges, dents or other irregularities.

Inspection of the bending mechanisms

Perform the following inspections while the bending section is straight.

WARNING

If the movement of the UP/DOWN angulation lock, RIGHT/LEFT angulation lock, and the angulation control knobs are loose and/or not smooth, or the bending section does not angulate smoothly, the bending mechanism may be abnormal. In this case, do not use the endoscope because it may be impossible to straighten the bending section during an examination.

Inspection for smooth operation

1. Confirm that both the UP/DOWN and RIGHT/LEFT angulation locks move all the way in the "F▶" direction.
2. Turn the UP/DOWN and RIGHT/LEFT angulation control knobs slowly in each direction until they stop, and return them to their respective neutral positions. Confirm that the bending section angulates smoothly and correctly, that maximum angulation can be achieved, and that the bending section returns to its neutral position.
3. When the UP/DOWN and RIGHT/LEFT angulation control knobs are turned to their respective neutral positions as shown in Figure 3.4, confirm that the bending section returns smoothly to an approximately straight condition.

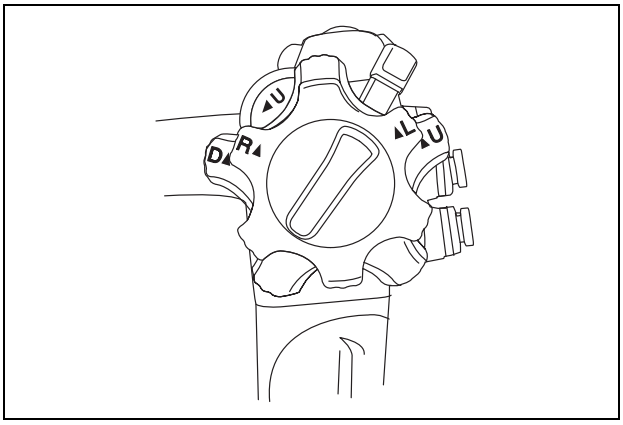


Figure 3.4

Inspection of the UP/DOWN angulation mechanism

1. Move the UP/DOWN angulation lock all the way in the opposite direction of the "F▶" mark. Then turn the UP/DOWN angulation control knob in the "▲U" or the "D▲" direction until it stops.
2. Confirm that the angle of the bending section is roughly stabilized when the UP/DOWN angulation control knob is released.
3. Confirm that the bending section straightens out when the UP/DOWN angulation lock is moved all the way in the "F▶" direction and the UP/DOWN angulation control knob is released.

❍ Inspection of the RIGHT/LEFT angulation mechanism

1. Turn the RIGHT/LEFT angulation lock all the way in the opposite direction of the “F▶” mark. Then turn the RIGHT/LEFT angulation control knob in the “R▲” or the “▲L” direction until it stops.
2. Confirm that the angle of the bending section is roughly stabilized when the RIGHT/LEFT angulation control knob is released.
3. Confirm that the bending section straightens out when the RIGHT/LEFT angulation lock is turned in the “F▶” direction and the RIGHT/LEFT angulation control knob is released.

Inspection of the forceps elevator mechanism

Perform the following inspections while the bending section is straight.

WARNING

Move the elevator control lever slowly in the opposite direction of the “◀U” direction until it stops and visually confirm that the portion of the elevator wire extending from the distal end of the insertion section is not broken or bent. If the elevator wire is broken or bent, patient injury, bleeding, and/or perforation could result.

❍ Inspection for smooth operation

1. Move the elevator control lever slowly all the way in the opposite direction of the “◀U” direction. Visually confirm that the portion of the elevator wire extending from the distal end of the insertion section is not broken or bent (see Figure 3.5).
2. While observing the forceps elevator at the distal end of the insertion section, slowly move the elevator control lever all the way in the “◀U” direction. Confirm that the lever can be operated smoothly and that the forceps elevator is raised smoothly. Also confirm that the forceps elevator remains stationary when pushed from behind while holding the elevator control lever stationary (see Figure 3.5).
3. Move the elevator control lever slowly all the way in the opposite direction of the “◀U” direction. Confirm that the lever can be operated smoothly and that the forceps elevator is lowered smoothly (see Figure 3.5).

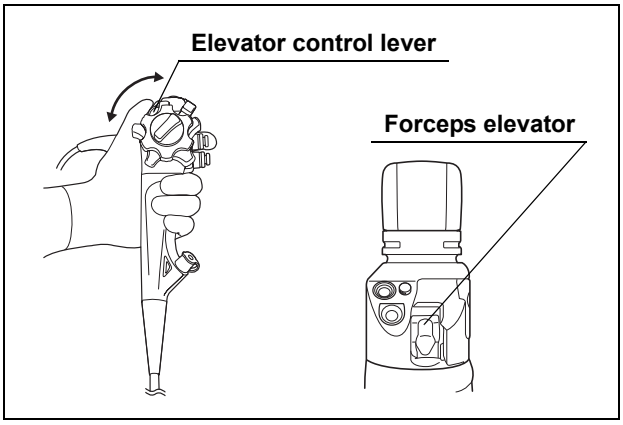


Figure 3.5

3.3 Preparation and inspection of accessories

Clean and disinfect or sterilize the air/water valve, suction valve, biopsy valve as described in Chapter 7, “Cleaning, Disinfection, and Sterilization Procedures”.

Inspection of the air/water and suction valves

WARNING

Confirm that the top hole of the air/water valve is not blocked (see Figure 3.6). If the hole is blocked, air is fed continuously and patient pain, bleeding, and/or perforation can result.

1. Confirm that the holes of the valves are not blocked (see Figures 3.6 and 3.7).
2. Confirm that the valves are not deformed or cracked (see Figures 3.6 and 3.7).
3. Check for excessive scratching or tears in the air/water valve’s seals (see Figure 3.6).

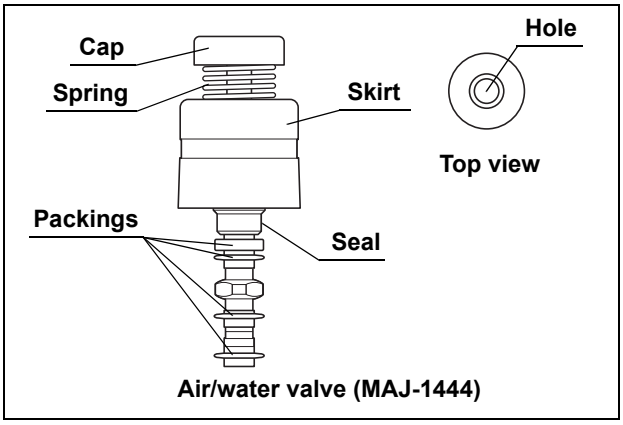


Figure 3.6

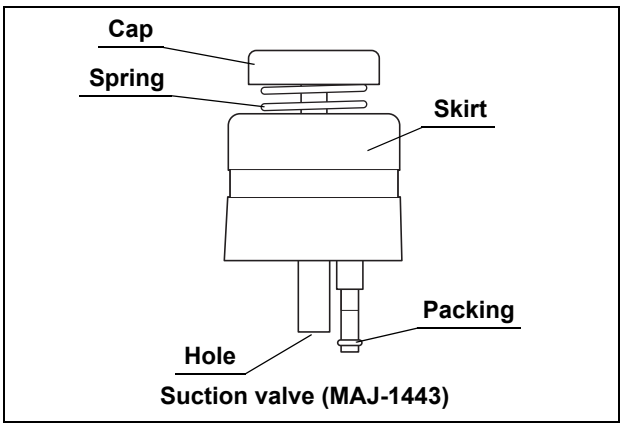


Figure 3.7

NOTE

The air/water and suction valves are consumables. If the inspection of the air/water or suction valve reveals any irregularity, use new valves.

Inspection of the biopsy valve

WARNING

The biopsy valve is a consumable that should be inspected as follows before each use. Replace it with a new one if any irregularity is observed during the inspection. An irregular, abnormal, or damaged valve can reduce the efficacy of the endoscope's suction system, and may leak or spray patient debris or fluids, posing an infection control risk.

1. Confirm that the slit and hole on the biopsy valve have no splits, cracks, deformations, discoloration, or other damage (see Figure 3.8).

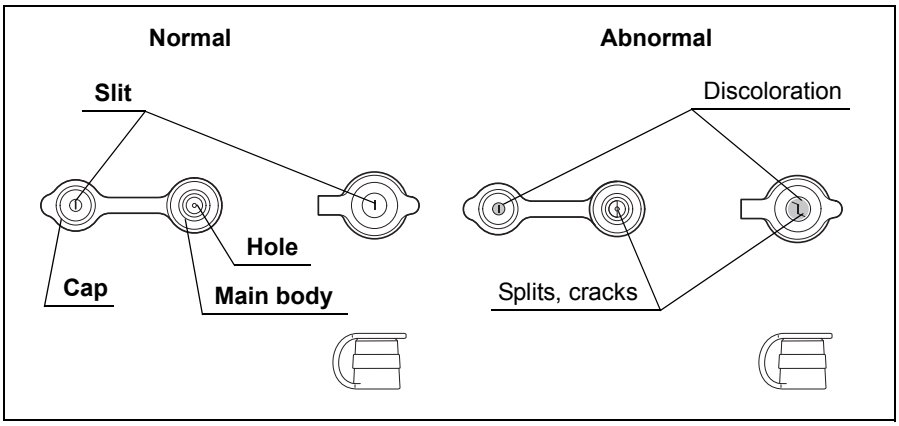


Figure 3.8

2. Attach the cap to the main body (see Figure 3.9).

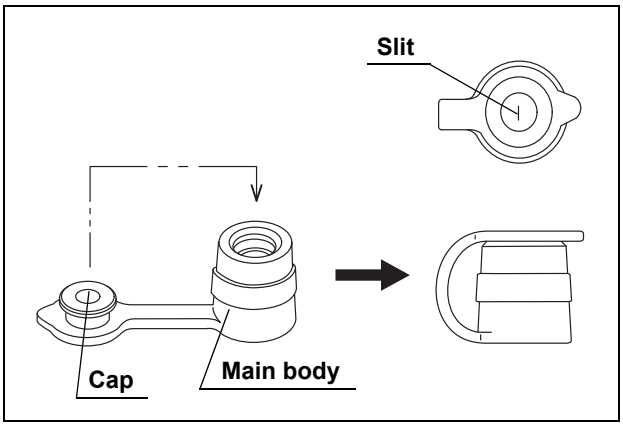


Figure 3.9

Inspection of the mouthpiece

CAUTION

Do not use a mouthpiece that is damaged, deformed, or reveals other irregularities. Doing so may cause patient injury and/or equipment damage.

NOTE

Placing the mouthpiece in the patient's mouth before the procedure prevents the patient from biting and/or damaging the endoscope's insertion section.

1. Confirm that the mouthpiece is free from cracks, deformations, or discoloration (see Figure 3.10).
2. Using your fingers, check all surfaces of the mouthpiece for scratches, cracks, or other irregularities (see Figure 3.10).

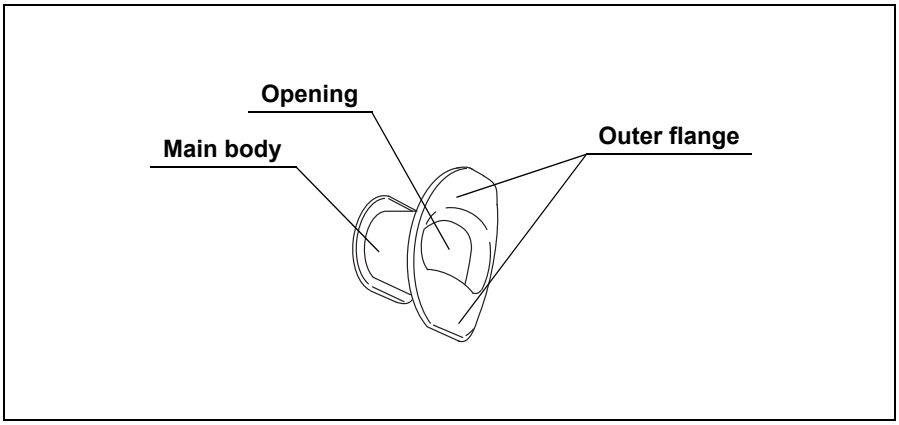


Figure 3.10

3.4 Attaching accessories to the endoscope

CAUTION

The air/water valve and the suction valve do not require lubrication. Lubricants can cause swelling of the valves' seals, which will impair valve function.

Attaching the suction valve

Attach the suction valve (MAJ-1443) to the suction cylinder of the endoscope (see Figure 3.11). Confirm that valve is fitted properly without any bulging of the skirt.

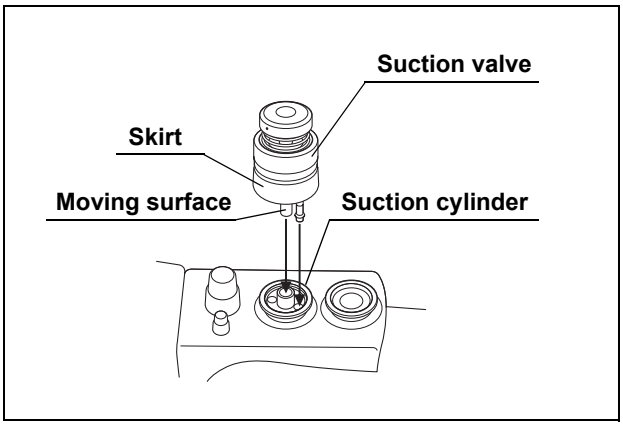


Figure 3.11

NOTE

The suction valve will make a whistling noise when it is dry; this does not indicate a malfunction.

Attaching the air/water valve

Attach the air/water valve (MAJ-1444) to the air/water cylinder of the endoscope (see Figure 3.12). Confirm that valve is fitted properly without any bulging of the skirt.

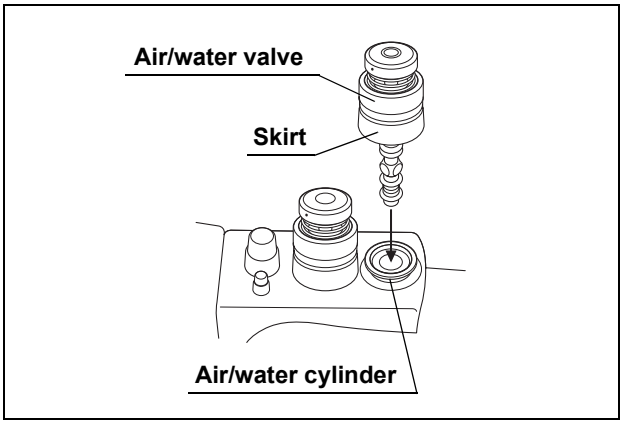


Figure 3.12

NOTE

The air/water valve may stick at first, but it should operate smoothly after it is depressed a few times.

Attaching the biopsy valve

WARNING

If a biopsy valve is not properly connected to the instrument channel port, it can reduce the efficacy of the endoscope's suction system, and leak or spray patient debris, posing an infection control risk.

Attach the biopsy valve to the instrument channel port of the endoscope (see Figure 3.13). Confirm that the biopsy valve fits properly.

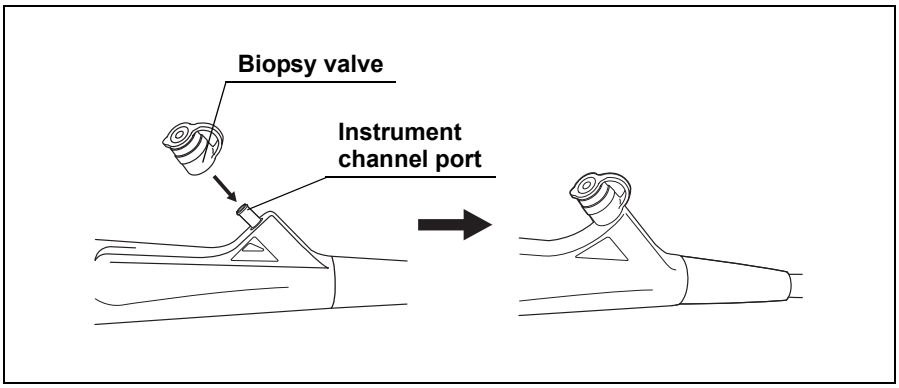


Figure 3.13

3.5 Inspection and connection of ancillary equipment

Inspection of ancillary equipment

CAUTION

- Attach the water container to the specified receptacle on the trolley (cart) or the light source. If the water container is attached anywhere else, water may drip from the water container's water supply tube, and equipment malfunction can result.
- Take care not to spill water from the water container's connection adapter when detaching the connection adapter from the endoscope. Spilled water could splash on the equipment, and may cause equipment malfunction.

1. Prepare and inspect the light source, video system center, ultrasound diagnostic equipment, monitor, water container, suction pump, and EndoTherapy accessories as described in their respective instruction manuals.
2. Confirm that there are no scratches, cracks, excessive wear, or deformation of the ultrasonic cable.

Connection of the ultrasonic cable (MAJ-1597) and Olympus universal endoscopic ultrasound center

Insert the ultrasonic connector properly into the transducer port of the Olympus universal endoscopic ultrasound center. Rotate the connector's lock handle 1/4 turn clockwise (see Figure 3.14).

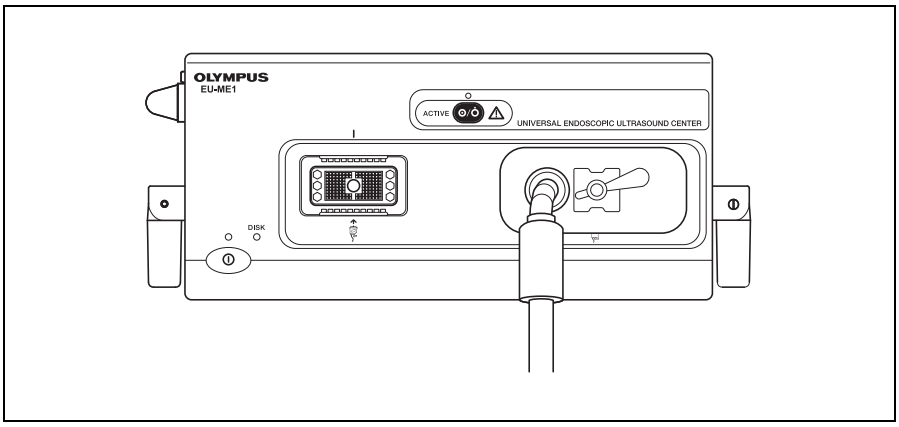


Figure 3.14

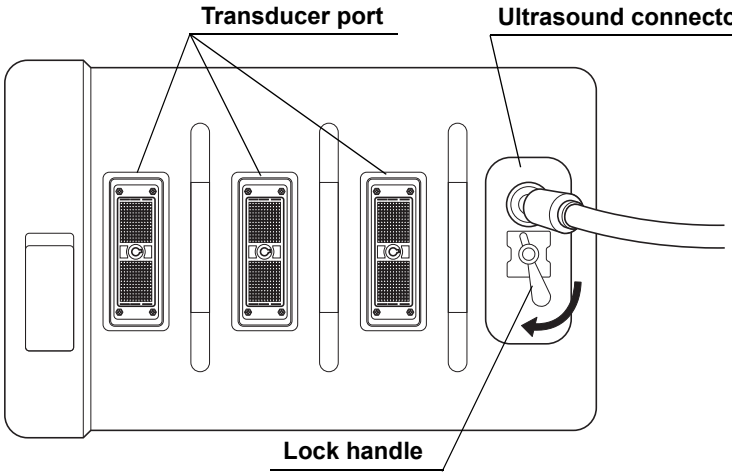
Connection of the ultrasonic cable (MAJ-1597) and ALOKA diagnostic ultrasound system

Insert the ultrasound connector properly into the transducer port of the diagnostic ultrasound system. Rotate the connector's lock handle 1/4 turn clockwise (see Figure 3.15).

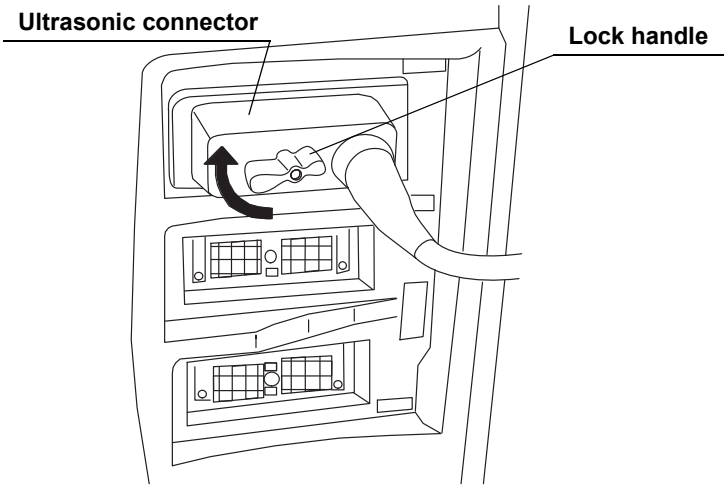
CAUTION

Connect the Ultrasound connector to one of the probe connectors on the lower side (PROBE 3 or 4) of the ProSound F75 (see Figure 3.15).
If the Ultrasound connector is connected to one of the probe connectors on the upper side (PROBE 1 or 2) , the operation panel of the ProSound F75 may hit the Ultrasound connector, which may result in the equipment damage. When adjusting the height, a horizontal and / or vertical position of the operation panel of the ProSound F75 with the Ultrasound connector connected to the PROBE 1 or 2, move slowly the operation panel with visually confirming the position of the bottom of the operation panel.

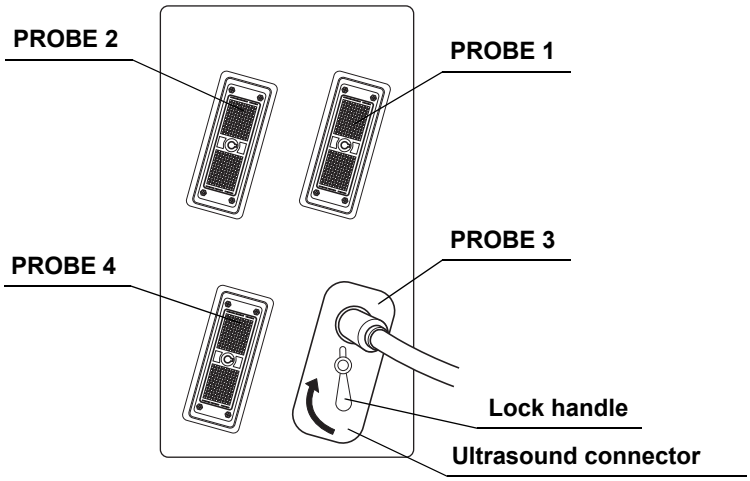
SSD-α10



ProSound α7[*1]



ProSound F75[*1]



∗1 These products may not be available in some areas.

Figure 3.15

Connection of the endoscope and ancillary equipment

WARNING

Firmly connect the suction tube from the suction pump to the suction connector on the endoscope connector. If the suction tube is not attached properly, debris may drip from the tube and can pose an infection control risk, cause equipment damage, and/or reduce suction capability.

CAUTION

The electrical contacts inside the ultrasound connector may be damaged by handling. Do not touch the electrical contacts. If electrical contacts are dirty, wipe the contacts with a soft and lint-free cloth.

1. If any ancillary equipment is ON, turn it OFF.
2. Insert the endoscope connector completely into the output socket of the light source.
3. Make sure that the inside of the videoscope cable connector is dry and free of debris.
4. Place the water container's water supply channel onto the water supply connector on the endoscope connector at an angle of 90° and push it in until it stops (see Figure 3.16 (1)).
5. Turn the water container's connection adapter 90° clockwise to align the air supply channel with the air supply connector of the endoscope connector (see Figure 3.16 (2)).
6. Push the water container's connection adapter again until it stops (see Figure 3.16 (3)).
7. Confirm that the water container's connection adapter fits properly and that it cannot be rotated (see Figure 3.16 (4)).

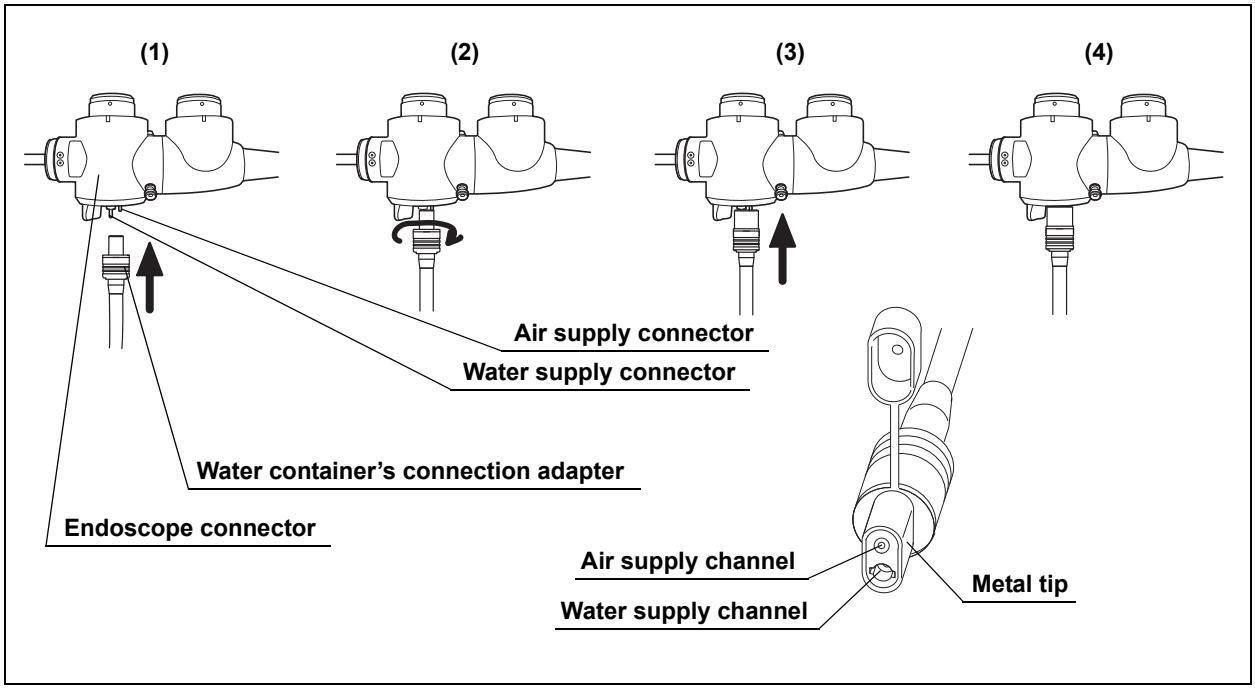


Figure 3.16

8. Align the mark on the videoscope cable with mark 1 on the endoscope connector and push it in until it stops (see Figure 3.17).

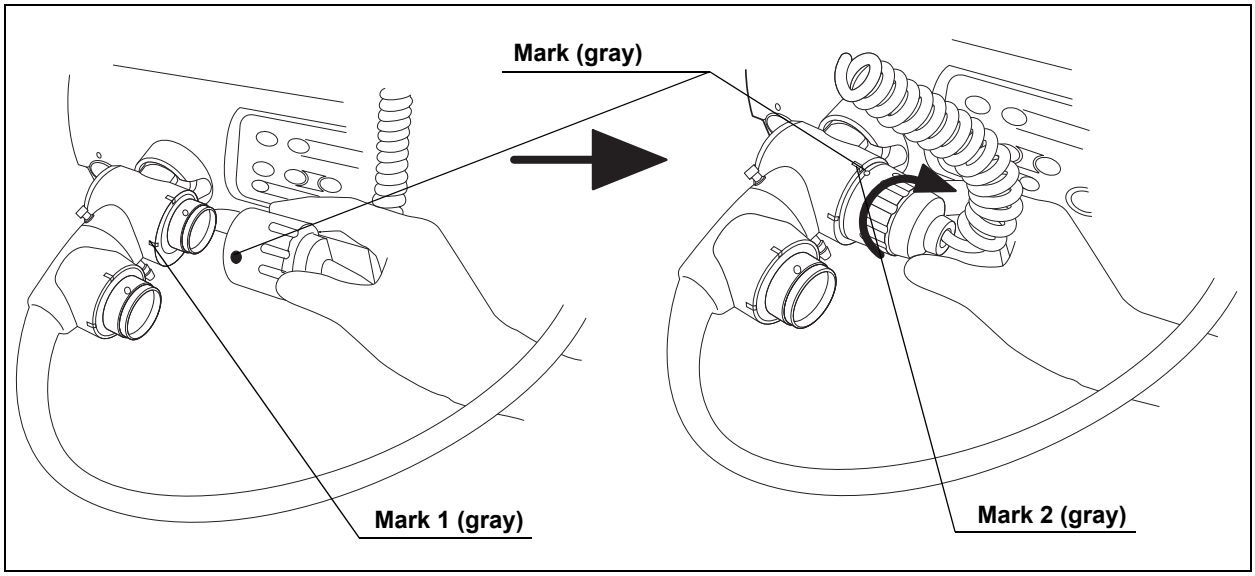


Figure 3.17

9. Turn the connector of the videoscope cable towards mark 2 until it stops (see Figure 3.17).

10. Confirm that the mark on the videoscope cable is aligned with mark 2 on the endoscope connector.

11. Connect the suction tube from the suction pump to the suction connector on the endoscope connector (see Figure 3.18).

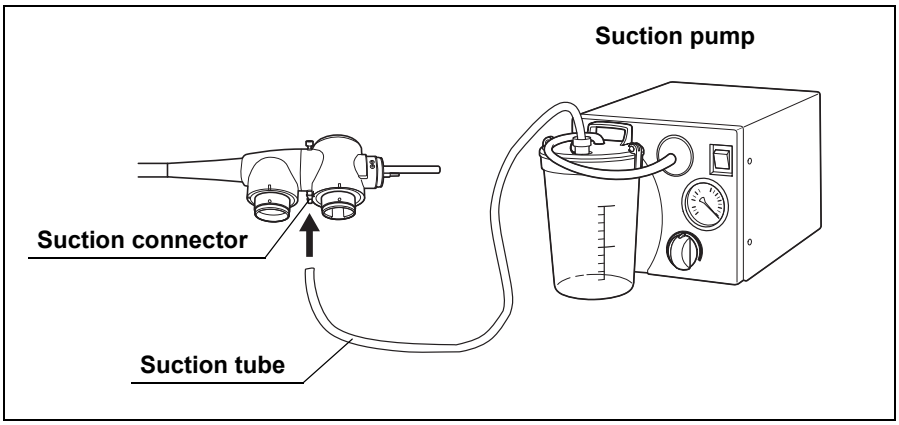


Figure 3.18

Connection of the endoscope and ultrasonic cable

WARNING

The electrical contacts inside the ultrasound connector have sharp tips and may be damaged by handling. Do not touch the electrical contacts.

CAUTION

For more information on combining the endoscope with the ultrasonic cable, refer to the “System chart” in the Appendix. When connect the endoscope-side connector of the ultrasonic cable to the ultrasonic cable connector, do not entwine the universal cord with the ultrasonic cable. Equipment damage can result.

1. Make sure that the inside of the ultrasonic cable connector is dry and free of debris.
2. Align the mark on the ultrasonic cable with mark A on the ultrasound connector and push it until it stops (see Figure 3.19).
3. Turn the endoscope-side connector of the ultrasonic cable clockwise until it stops (see Figure 3.19).
4. Confirm that the mark on the ultrasonic cable is aligned with mark B on the endoscope connector (see Figure 3.19).

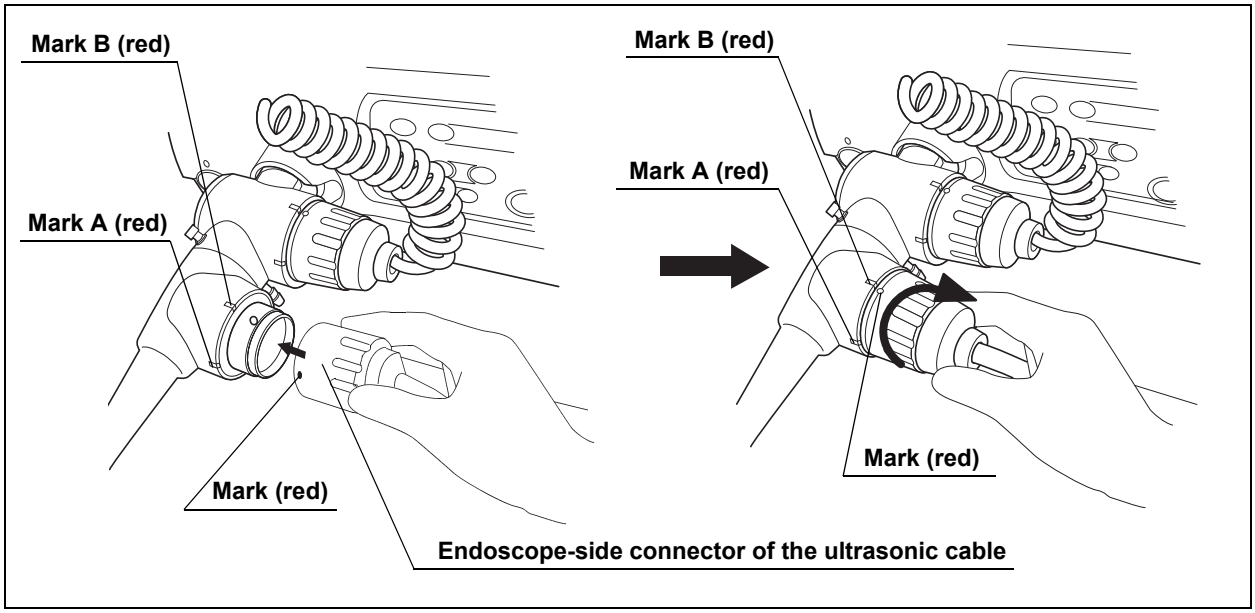


Figure 3.19

3.6 Inspection of the endoscopic system

Inspection of the endoscopic image

WARNING

Do not stare directly into the distal end of the endoscope while the examination light is ON. Otherwise, eye injury may result.

1. Turn the video system center, light source, and monitor ON and inspect the WLI and NBI endoscopic image as described in their respective instruction manuals.
2. Confirm that light is output from the endoscope's distal end.
3. While observing the palm of your hand, confirm that the WLI and NBI endoscopic image is free from noise, blur, fog, or other irregularities.
4. Angulate the endoscope and confirm that the WLI and NBI endoscopic image does not momentarily disappear or display any other irregularities.

NOTE

If the object cannot be seen clearly, wipe the objective lens using a clean, lint-free cloth moistened with 70% ethyl or isopropyl alcohol.

Inspection of the remote switches

WARNING

All remote switches should be checked prior to the examination, even when they are not expected to be used. The endoscopic image may freeze, or other irregularities may occur during examination and may cause patient injury, bleeding, and/or perforation.

Depress every remote switch and confirm that the specified functions work normally.

Inspection of the air-feeding function

1. Set the airflow regulator on the light source to “High”, as described in the light source’s instruction manual.
2. Immerse the distal end of the insertion section in sterile water to a depth of 10 cm and confirm that no air bubbles are emitted when the air/water valve is not operated.
3. Cover the hole in the air/water valve with your finger and confirm that air bubbles are continuously emitted from the air/water nozzle.
4. Uncover the hole in the air/water valve and confirm that no air bubbles are emitted from the air/water nozzle.

WARNING

If a stream of air bubbles is emitted from the air/water nozzle even though the air/water valve is not being operated and the distal end of the insertion section is 10 cm or more below the surface of the sterile water, there may be an irregularity in the air-feeding function. If the endoscope is used while air is continuously fed, over-insufflation and patient injury may result. If air bubbles are emitted from the air/water nozzle, remove and reattach the air/water valve correctly, or replace it with a new one. If this fails to stop air bubbles from being emitted, do not use the endoscope because there may be a malfunction. Contact Olympus.

NOTE

When the distal end of the insertion section is immersed less than 10 cm below the surface of the sterile water, a small amount of air bubbles may be emitted from the air/water nozzle even when the air/water valve is not operated. This does not indicate a malfunction.

Inspection of the objective lens cleaning function

WARNING

Use sterile water only. Nonsterile water may cause patient cross-contamination and/or infection.

NOTE

- When the air/water valve is depressed for the first time, it may take a few seconds before water is emitted.
- If the air/water valve returns to its original position slowly after water feeding, remove the air/water valve and moisten the seals with sterile water.
- During the inspection, place the distal end of the endoscope in a beaker or other container so that the floor does not get wet.

1. Keep the air/water valve's hole covered with your finger and depress the valve to the first stage. Observe the endoscopic image and confirm that water flows on the entire objective lens.
2. Release the air/water valve. While observing the endoscopic image, confirm that the emission of water stops and that the valve returns smoothly to its original position.
3. While observing the endoscopic image, feed air after feeding water by covering the hole in the air/water valve with your finger. Confirm that the emitted air removes the remaining water from the objective lens and clears the endoscopic image.

Inspection of the water feeding function into the balloon

Cover the air/water valve's hole and completely depress the valve. Confirm that water is emitted through the balloon water supply port. It may take a few seconds until water is emitted when the air/water valve is depressed for the first time.

Inspection of the suction function

WARNING

- If the suction valve does not operate smoothly, detach it and reattach it, or replace it with a new one. If the endoscope is used while the suction valve is not working properly, it may be impossible to stop suction, which could cause patient injury. If the reattached or replaced suction valve fails to operate smoothly, the endoscope may be malfunctioning; stop using it and contact Olympus.
- If the biopsy valve leaks, replace it with a new one. A leaking biopsy valve can reduce the efficacy of the endoscope's suction system and may leak or spray patient debris or fluids, posing an infection control risk.

1. Place the container of sterile water and the endoscope at the same height. For the inspection, adjust the suction pressure to the same level as it will be during the procedure.
2. Immerse the distal end of the insertion section in sterile water with the endoscope's instrument channel port at the same height as the water level in the water container. Press the suction valve and confirm that water is continuously aspirated into the suction bottle of the suction pump.
3. Release the suction valve. Confirm that suction stops and the valve returns to its original position.
4. Depress the suction valve to the first stage and aspirate water for one second. Then, release the suction valve for one second. Repeat this several times and confirm that no water leaks from the biopsy valve.
5. Remove the distal end of the endoscope from the water. Depress the suction valve and aspirate air for a few seconds to remove any water from the instrument and suction channels.

Inspection of aspiration from the balloon water suction port

1. Immerse the distal end of the insertion tube in sterile water and completely depress the suction valve. Confirm that water is continuously aspirated.
2. Release the suction valve. Confirm that suction stops and the suction valve returns to its original position.
3. Remove the distal end from the water.

Inspection of the instrument channel and forceps elevator

WARNING

Keep your eyes away from the distal end when inserting EndoTherapy accessories. Extending the EndoTherapy accessory from the distal end could cause eye injury.

1. Confirm that the forceps elevator is lowered, then insert the EndoTherapy accessory through the biopsy valve. Confirm that the EndoTherapy accessory extends smoothly from the distal end, and that a foreign object does not come out.
2. Extend the EndoTherapy accessory approximately 3 cm from the distal end. Move the elevator control lever in the "◀U" direction and confirm that the forceps elevator is raised smoothly.
3. Move the elevator control lever in the opposite direction of the "◀U" direction and confirm that the forceps elevator is lowered.
4. Confirm that the EndoTherapy accessory can be withdrawn smoothly from the biopsy valve.

Inspection of the ultrasound image with the Olympus universal endoscopic ultrasound center EU-ME1

1. Turn on Olympus universal endoscopic ultrasound center EU-ME1.

NOTE

A progress bar is displayed after connecting the ultrasound endoscope (see Figure 3.20). During displaying the progress bar, the information on the connected ultrasonic endoscope has been updated to the ultrasound center. Do not turn OFF the ultrasound center while the progress bar is displayed.

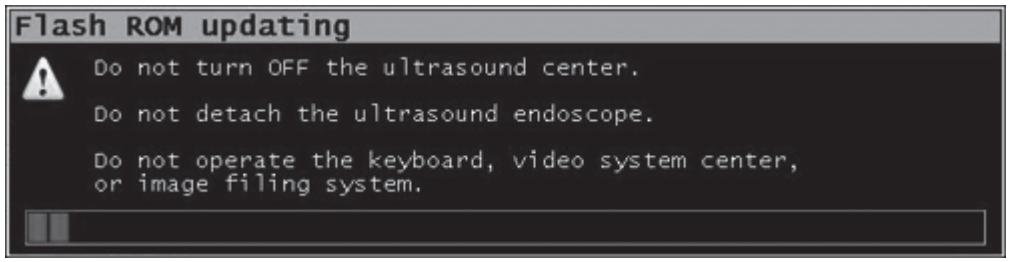

Flash ROM updating
Do not turn OFF the ultrasound center.
Do not detach the ultrasound endoscope.
Do not operate the keyboard, video system center,
or image filing system.

Figure 3.20

2. Inspect the endoscopic ultrasound center as described in its instruction manual.

3. When setting the frequency, choose the setting value CLA2, and then the frequencies available with the keyboard (see Figure 3.21). Refer to EU-ME1's instruction manual for instructions on how to set the frequency.

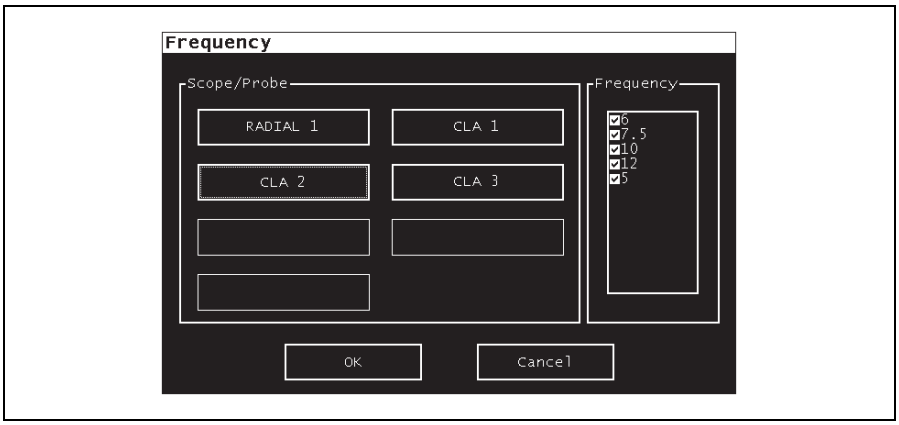


Figure 3.21

4. Press the "FREEZE" switch on the diagnostic ultrasound system to change the ultrasound image to the REAL-TIME mode.

5. Confirm that the ultrasound image is visible on the endoscopic ultrasound center (see Figure 3.22).

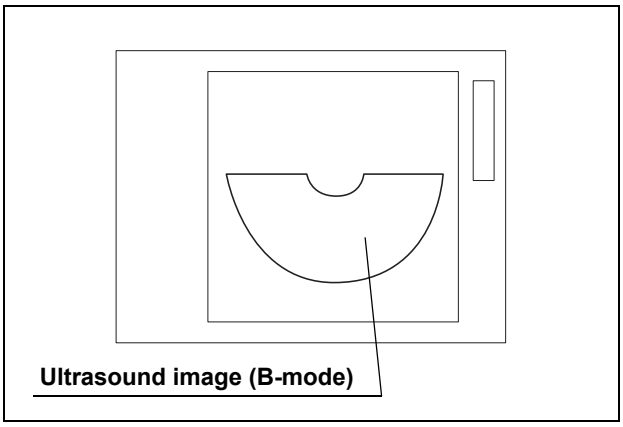


Figure 3.22

6. Press the "FREEZE" switch to change the ultrasound image to the FREEZE mode.

Inspection of the ultrasound image with the ALOKA diagnostic ultrasound system

1. Inspect the diagnostic ultrasound system as described in its instruction manual.
2. Turn the diagnostic ultrasound system ON.
3. Confirm that the ultrasound image is visible on the diagnostic ultrasound system (see Figure 3.23).

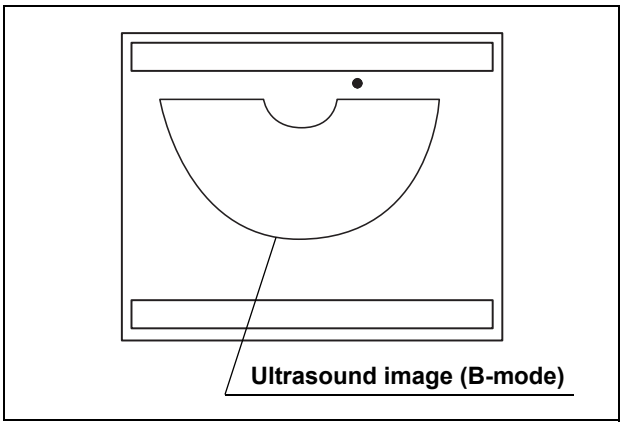


Figure 3.23

4. Press the “FREEZE” switch to change the ultrasound image to the FREEZE mode.

3.7 Preparation and inspection of the balloon

WARNING

- Balloons used with this instrument contain natural rubber latex that may cause allergic reactions in some individuals. Do not use the balloon on a latex-sensitive patient. Instead, perform the procedure using “The sterile deaerated water immersion method” described in Section 4.2, “Observation of the ultrasound image” on page 64.
- When using the sterile balloon (MAJ-249), do not use an instrument after the expiration date displayed on the sterile package. Doing so may pose an infection control risk.
- The balloons are disposable, and are intended for a single-use only. A new one must be used for each patient. Do not attempt to reuse the balloon. This could pose an infection-control risk or cause equipment damage.

- Confirm that the balloon applicator (MAJ-675) and cotton thread that is used to tie the balloon have been properly reprocessed as described in Chapters 5, “Reprocessing: General Policy” through 7, “Cleaning, Disinfection, and Sterilization Procedures”.
- If you find that a sterile balloon’s peel pack is open, damaged, or soiled, do not use that balloon.
- When using the sterile balloon (MAJ-249), inspect the sterile package for tears, inadequate sealing, or water damage. If the sterile package shows any irregularity, the sterile condition of the instrument may have been compromised.

CAUTION

- The balloons and the balloon applicator to be used with this endoscope are listed below. Balloon[*1] is provided clean and should be ETO gas sterilized before use. Balloon 3 is shipped sterile.

Balloon (nonsterile)	MAJ-213
Balloon 3 (sterile)	MAJ-249
Balloon applicator	MAJ-675

  ∗1 This item is not available in the USA.

- The balloon can easily tear, so beware of sharp objects.
- Store the balloon in a cool environment with low humidity.
- The resealable package containing the balloons also contains a deoxidizer to maintain a deoxygenated condition until the sterile peel pack is opened. After the resealable package is opened, the balloons will gradually deteriorate. To minimize deterioration, always keep the package sealed.
- The balloon applicator is reusable and supplied nonsterile.

Prepare the balloon and the balloon applicator.

Attaching the balloon

1. Inspect the balloon and confirm that there are no holes, swelling, color changes or any other irregularities. If an irregularity is detected, do not use the balloon; use a spare instead, inspecting it thoroughly before use.
2. Insert the front end of the balloon into the installation side of the balloon applicator. Slide the rear band of the balloon into the groove of the balloon applicator (see Figure 3.24).

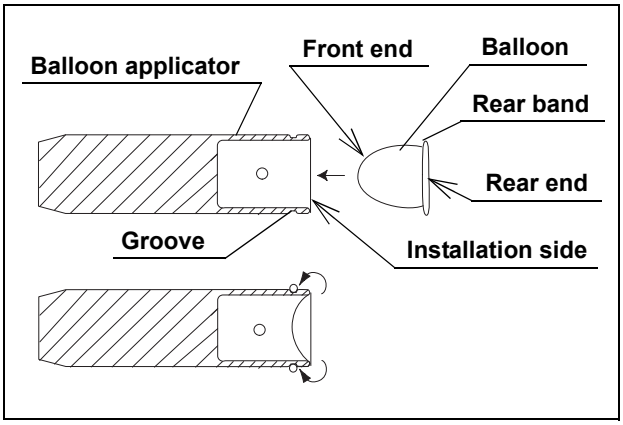


Figure 3.24

3. Insert the distal end of the endoscope into the balloon applicator until it contacts the front end of the balloon.
4. Remove the rear band from the balloon applicator and attach it to the endoscope's balloon attachment groove (see Figure 3.25).

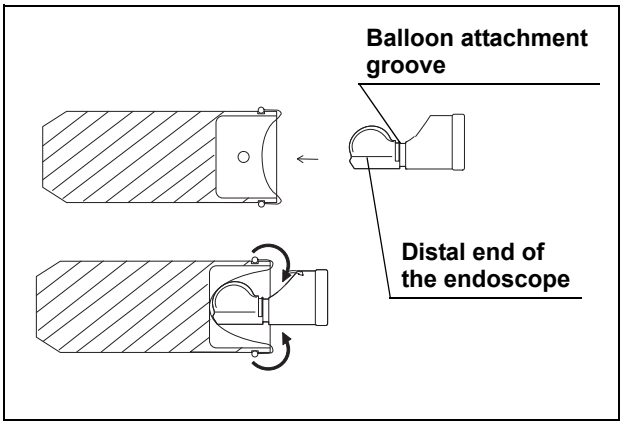


Figure 3.25

CAUTION

Do not apply excessive force to the distal end of the endoscope or bend it. Instrument damage may occur.

5. Remove the balloon applicator from the endoscope.

Inspection of the balloon and expelling air

CAUTION

- Do not feed water into the balloon when the water level in the water container is too low. The balloon may not be inflated properly. If this occurs, refer to Section 10.1, “Troubleshooting guide” on page 154.
- Disconnecting the water container from the endoscope just after removing the air bubbles from the balloon may cause them to reenter the balloon when inflating the balloon again. Therefore, confirm that there are no air bubbles in the balloon according to the following procedure.

1. Check the water level in the water container. If the water level is low, fill the water container with sterile deaerated water. After adding water to the water container or removing the water container from the endoscope, cover the hole in the air/water valve and depress it to the first stage for about 15 seconds. Turn the light source and suction pump ON.
2. Cover the hole in the air/water valve and completely depress the valve to fill the balloon with deaerated water.
3. Fill the balloon with deaerated water to a diameter of approximately 3 cm. Remove your finger from the air/water valve. If the balloon is eccentrically shaped after inflation, gently hold the balloon and turn it around. Confirm that there are no holes or other irregularities in the balloon.
4. Confirm that there are no air bubbles in the balloon.
5. If the balloon has no air bubbles in it, completely depress the suction valve until all the water has been aspirated from the balloon.
6. If air bubbles are observed in the balloon, lower the distal end of the endoscope and repeat Steps 2 through 5 until they are completely removed from the balloon. After confirming that all air bubbles have been removed, repeat Steps 2 through 5 two times to make sure they are completely removed.
7. Completely depress the suction valve until all the water has been aspirated from the balloon.
8. Tie the rear end of the balloon tightly with a sterile cotton thread.

CAUTION

Do not obstruct the balloon water supply port with the cotton thread. If the balloon water supply port is obstructed, the balloon cannot be inflated or deflated (see Figure 3.26).

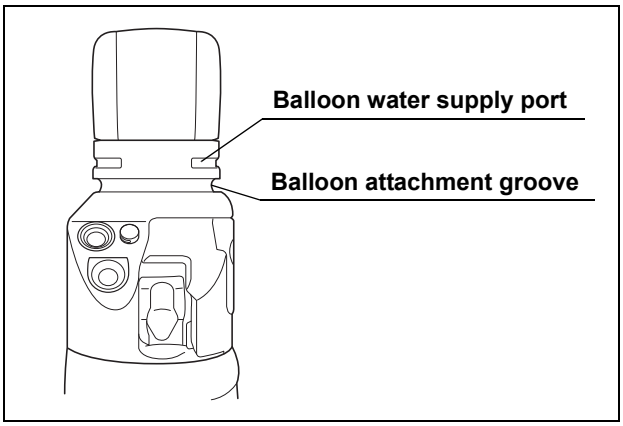


Figure 3.26

Chapter 4 Operation

This manual does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of this instrument. Therefore, the operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique.

WARNING

- To guard against dangerous chemicals and potentially infectious material during the procedure, wear personal protective equipment, such as eyewear, face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed.
- The temperature of the distal end of the endoscope may exceed 41°C (106°F) and reach 50°C (122°F) due to intense endoscopic illumination. Surface temperatures over 41°C (106°F) may cause mucosal burns. Always maintain a suitable distance necessary for adequate viewing while using the minimum level of illumination for the minimum amount of time. Do not use close stationary viewing or leave the distal end of the endoscope close to the mucous membrane for a long time without necessity.
- Whenever possible, do not leave the endoscope illuminated before and/or after an examination. Continued illumination will cause the distal end of the endoscope to become hot and could cause operator and/or patient burns.
- Turn the video system center ON to operate the light source's automatic brightness function. When the video system center is OFF, it cannot operate the light source's automatic brightness function, and the light intensity is set to the maximum level. In this case, the distal end of the endoscope can become hot and could cause operator and/or patient burns, when using the light source CLV-160, CLV-U40.

- Never insert or withdraw the endoscope under any of the following conditions. Otherwise, patient injury, bleeding, and/or perforation can result.
  - While the EndoTherapy accessory extends from the distal end of the endoscope.
  - While the bending section is locked in position.
  - Insertion or withdrawal with excessive force.
  - Insertion or withdrawal while the forceps elevator is raised.
- If any of the following phenomena occur during an examination, immediately stop the examination and withdraw the endoscope from the patient as described in Section 10.2, “Withdrawal of the endoscope with an irregularity” on page 159.
  - Should any irregularity be observed with the functionality of the endoscope.
  - If the endoscopic image on the monitor disappears or freezes unexpectedly.
  - If the angulation control knob is locked.
  - If the angulation control mechanism is not functioning properly.

  Continued use of the endoscope under these conditions could result in patient injury, bleeding, and/or perforation.
- If an abnormal endoscopic image or function occurs, but quickly corrects itself, the endoscope may have malfunctioned. In this case, stop using the endoscope because the irregularity can occur again and the endoscope may not return to its normal condition. Therefore, stop the examination immediately and slowly withdraw the endoscope while viewing the endoscopic image. Otherwise, patient injury, bleeding, and/or perforation can result.
- The endoscopic image may be disturbed while switching between WLI observation mode and NBI observation mode. Therefore, do not perform an endoscopic operation or treatment while switching between WLI observation mode and NBI observation mode. Otherwise, injury in the body cavity may result.

NOTE

- Set the brightness of the light source to the minimum level necessary to perform the procedure safely. If the endoscope is used for a prolonged period at or near maximum light intensity, vapor may be observed in the endoscopic image. This is caused by the evaporation of organic material (blood, moisture in stool, etc.) due to heat generated by the light guide near the light guide lens. If this vapor continues to interfere with the examination, remove the endoscope, wipe the distal end with a lint-free cloth moistened with 70% ethyl or isopropyl alcohol, reinsert the endoscope, and continue the examination.
- The color tone and brightness of NBI observation mode is different from WLI observation mode. Use NBI observation mode only when fully understanding its features.

4.1 Insertion

Holding and manipulating the endoscope

The control section of the endoscope is designed to be held in the left hand. The air/water and suction valves can be operated using the left index finger. The UP/DOWN angulation control knob and the elevator control lever can be operated using the left thumb. The right hand is free to manipulate the insertion section and the RIGHT/LEFT angulation control knob (see Figure 4.1).

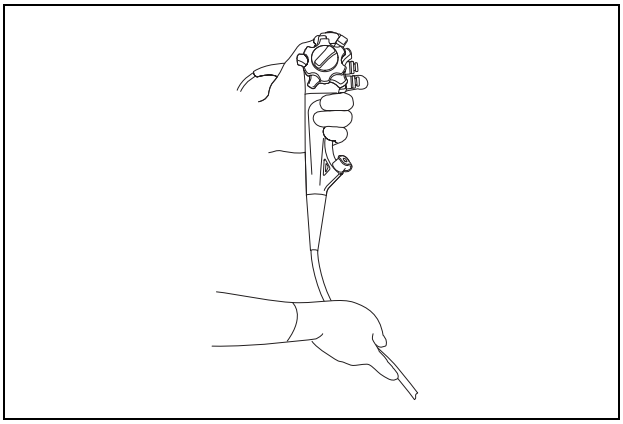


Figure 4.1

Insertion of the endoscope

WARNING

Keep the elevator control lever moved all the way in the opposite direction of the "◀U" direction while inserting or withdrawing the endoscope into or from the patient. If the elevator control lever is moved all the way in the "◀U" direction and the forceps elevator is raised while inserting or withdrawing the endoscope into or from the patient, this may cause patient injury.

CAUTION

- To prevent the patient from accidentally biting the insertion section during an examination, it is strongly recommended that a mouthpiece be placed in the patient's mouth before inserting the endoscope.
- To prevent the patient from accidentally loosing dental prosthesis, make sure that the patient removes it before the examination.
- Do not apply olive oil or products containing petroleum-based lubricants (e.g., Vaseline®) to the endoscope. These products may cause stretching and deterioration of the bending section's covering.
- Do not allow the insertion section to be bent within a distance of 10 cm or less from the junction of the boot. Insertion section damage can occur (see Figure 4.2).

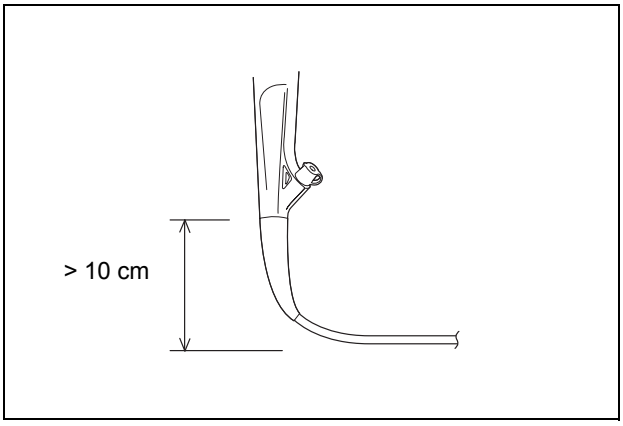


Figure 4.2

1. Move the elevator control lever in the opposite direction of the "◀U" until it stops.
2. If necessary, apply a medical-grade, water-soluble lubricant to the insertion section.
3. Place the mouthpiece between the patient's teeth or gums, with the outer flange on the outside of the patient's mouth.

Angulation of the distal end

CAUTION

Avoid forcible or excessive angulation as this imposes load on the wire controlling the bending section. This may cause stretching or tearing of the wire, which could impair the movement of the bending section.

1. Operate the angulation control knobs as necessary to guide the distal end for insertion and observation.
2. The endoscope's angulation locks are used to hold the angulated distal end in position.

NOTE

- When passing an EndoTherapy accessory through the instrument channel while the angulation is locked, the angle of the distal end may change. When it is necessary to keep the angulation stationary, hold the angulation control knobs in place with your hand.
- When operating the UP/DOWN or RIGHT/LEFT angulation lock, hold the angulation control knob stationary with your finger. If this is not done, the angulation will change.

Air/water feeding and suction

WARNING

- If the sterile water level in the water container is too low, then air, not water, will be supplied. In this case, turn the airflow regulator on the light source OFF and add sterile water to the water container until it reaches the specified water level.
- If air/water feeding does not stop, turn the airflow regulator on the light source OFF and replace the air/water valve with a new one.

- Before using a syringe to inject liquid through the biopsy valve, detach the valve's cap from the main body. Then insert the syringe straight into the valve and inject the liquid. If the cap is not detached and/or the syringe is not inserted straight, the biopsy valve could be damaged, which could reduce the efficacy of the endoscope's suction system, and may leak or spray patient debris or fluids, posing an infection control risk.
- If the biopsy valve is left uncapped during the procedure, debris or fluids could leak or spray from it, posing an infection control risk. When the valve is uncapped, place a piece of sterile gauze over it to prevent leakage.

NOTE

If the endoscope is cold, condensation may form on the surface of the objective lens and the endoscopic image may appear cloudy. In this case, increase the temperature of the sterile water in the water container to between 40 – 50°C (104 – 122°F) and then use the endoscope.

Air/water feeding

1. Cover the air/water valve's hole to feed air from the air/water nozzle at the distal end (see Figure 4.3).
2. Depress the air/water valve to the first stage to feed water onto the objective lens (see Figure 4.3).

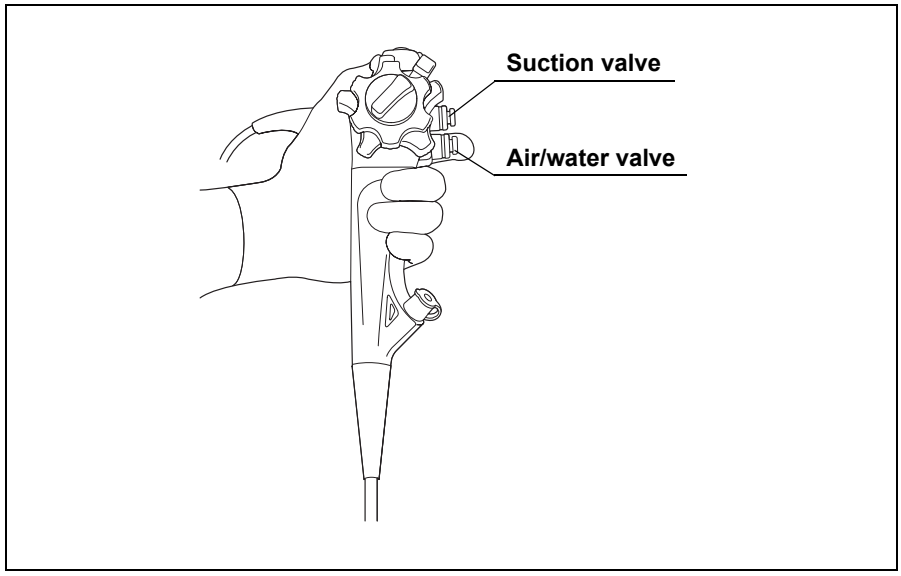


Figure 4.3

❍ Suction

WARNING

- Avoid aspirating solid matter or thick fluids; instrument channel, suction channel, or suction valve clogging can occur. If the suction valve clogs and suction cannot be stopped, disconnect the suction tube from the suction connector on the endoscope connector. Turn the suction pump OFF, detach the suction valve and remove solid matter or thick fluids.
- When aspirating, maintain the suction pressure at the lowest level necessary to perform the procedure. Excessive suction pressure could cause aspiration of and/or injury to the mucous membrane. In addition, patient fluids could leak or spray from the biopsy valve, posing an infection control risk.
- When aspirating, attach the cap to the main body of the biopsy valve. An uncapped biopsy valve can reduce the efficacy of the endoscope's suction system, and may leak or spray patient debris or fluids, posing an infection control risk.

CAUTION

During the procedure, make sure that the suction bottle does not fill completely. Aspirating fluids into a full bottle may cause the suction pump to malfunction.

Depress the suction valve to the first stage to aspirate excess fluid or other debris obscuring the endoscopic image (see Figure 4.3).

NOTE

Performing both air feeding and suction at the same time sometimes makes it easier to remove water droplets from the objective lens surface.

Observation of the endoscopic image

WARNING

Do not rely only on the NBI observation mode for primary detection of lesions or to make a decision regarding any potential diagnostic or therapeutic intervention.

Refer to the light source's instruction manual for instructions on how to adjust the brightness.

4.2 Observation of the ultrasound image

The sterile deaerated water immersion method

CAUTION

- Completely insert the water feeding valve (MD-744) of the water supply unit (UWS-1) into the biopsy valve (MAJ-853). Improper connection may cause water to leak.
- If no balloon is attached, do not depress the suction valve completely. The balloon channel may be clogged.

1. Position the distal end of the endoscope near the target site and push the “FREEZE” switch on the ultrasound system to change the ultrasound image to the REAL-TIME mode.
2. Connect the water supply unit’s water-feeding valve to the biopsy valve of the endoscope.
3. Depress the water supply unit’s water feeding valve as described in its instruction manual and supply the necessary amount of sterile deaerated water.

The balloon method

CAUTION

- Do not inflate the balloon to a diameter of more than 3 cm.
- Do not feed water into the balloon when the water level in the water container is too low. The balloon may not be inflated properly.

NOTE

If the water container is removed from the endoscope while inflating the balloon, cover the hole in the air/water valve and depress the valve to the first stage for about 15 seconds. By doing so, air bubbles can be prevented from entering the balloon.

1. Position the distal end of the endoscope near the target site and press the “FREEZE” switch on the ultrasound system to change the ultrasound image to the REAL-TIME mode.
2. Cover the small hole in the air/water valve of the endoscope and completely depress the valve to inflate the balloon.
3. While viewing the ultrasound image, inflate the balloon to the desired size. Do not inflate the balloon to a diameter greater than 3 cm.
4. Use the endoscope’s angulation mechanism to bring the balloon into full contact with the intestinal wall. Move the distal end to the target site.

Observation

CAUTION

Keep the ultrasound system in the FREEZE mode, except during ultrasound observation.

NOTE

When combined with another electrical instrument, noise may be displayed on the video monitor.

When the ultrasound image of the target appears, adjust the ultrasound system as described in its instruction manual to obtain a suitable image.

4.3 Using EndoTherapy accessories

For more information on combining the endoscope with particular EndoTherapy accessories, refer to the “System chart” in the Appendix and the instruction manuals for the accessories.

WARNING

- When using EndoTherapy accessories, keep the distance between the distal end of the endoscope and the mucous membrane greater than the endoscope’s minimum visible distance so that the EndoTherapy accessory remains visible in the endoscopic image. If the distal end of the endoscope is placed closer than its own minimum visible distance, the position of the accessory cannot be seen in the endoscopic image, which could cause serious patient injury and/or equipment damage. The minimum visible distance depends on the type of endoscope being used. Refer to Section 2.3, “Specifications” on page 21.
- When inserting or withdrawing an EndoTherapy accessory, confirm that its distal end is closed or completely retracted into the sheath. Slowly insert or withdraw the EndoTherapy accessory straight into/from the slit of the biopsy valve. Otherwise, the biopsy valve may be damaged and pieces of it could fall off.
- If the insertion or withdrawal of EndoTherapy accessories is difficult, straighten the bending section as much as possible without losing the endoscopic image. Inserting or withdrawing EndoTherapy accessories with excessive force may damage the instrument channel or EndoTherapy accessories and could cause some parts to fall off and/or cause patient injury.
- Do not switch between WLI observation mode and NBI observation mode while using an EndoTherapy accessory. The endoscopic image may be disturbed while switching between WLI observation mode and NBI observation mode. This could cause patient injury, bleeding, and/or perforation.
- If the distal end of an EndoTherapy accessory is not visible in the endoscopic image, do not open the distal end or extend the needle of the instrument. This could cause patient injury, bleeding, perforation, and/or equipment damage.

- Do not insert EndoTherapy accessories without the forceps elevator being raised. If they are inserted without the forceps elevator being raised, the accessory cannot be observed in the endoscopic image and it may cause patient injury.
- While raising the forceps elevator, do not insert or withdraw the EndoTherapy accessory with excessive force, open or close the distal end of the EndoTherapy accessory, or extend the needle of the instrument. This could damage the instrument channel and/or the EndoTherapy accessory and could cause patient injury, bleeding, and/or perforation. If the EndoTherapy accessory cannot be inserted or withdrawn, the distal end of the EndoTherapy accessory cannot be opened or closed, or the needle of the instrument cannot be extended, move the elevator control lever in the opposite direction of the "◀U" direction to lower the forceps elevator.
- If the forceps elevator cannot be lowered while using an EndoTherapy accessory, stop the procedure immediately and take appropriate measures.
- Do not inflate air or a nonflammable gas excessively into the patient. This could cause gas embolism.
- EUS guided FNA should only be performed when the needle is visible in the ultrasound image.
- If the ultrasound image disappears while using the needle, stop the procedure immediately and withdraw the needle from the tissue.

CAUTION

- When using a biopsy forceps with a needle, confirm that the needle is not excessively bent. A bent needle could protrude from the closed cups of the biopsy forceps. Using biopsy forceps with a protruding needle could damage the instrument channel and/or cause patient injury.
- When using an injector, be sure not to extend or retract the needle from the catheter of the injector until the injector is extended from the distal end of the endoscope. The needle could damage the instrument channel if extended inside the channel, or if the injector is inserted or withdrawn while the needle is extended.
- Although the color code is orange as with GF-UCT180, do not use EndoTherapy accessories designed for ø 4.2 mm channel, otherwise the endoscope and/or the EndoTherapy accessories may be damaged.

Insertion of EndoTherapy accessories into the endoscope

WARNING

- Do not insert EndoTherapy accessories forcibly or abruptly. Otherwise, the EndoTherapy accessory may extend from the distal end of the endoscope abruptly, which could cause patient injury, bleeding, and/or perforation.
- When the biopsy valve's cap is detached from the main body, it is easier to insert an EndoTherapy accessory into the instrument channel port (see Figure 3.9 on page 36). However, the open biopsy valve, after withdrawing an EndoTherapy accessory, can reduce the efficacy of the endoscope's suction system, and it may leak or spray patient debris or fluids, posing an infection control risk. When not using an EndoTherapy accessory, attach the cap to the main body of the biopsy valve.
- When the biopsy valve's cap is detached from the main body, it may cause patient debris or fluids to leak or spray from the endoscope, posing an infection control risk. When the biopsy valve's cap has to be detached, place a piece of sterile gauze over it to prevent leakage.
- Do not let the EndoTherapy accessory hang down from the biopsy valve. Doing so can create a space between the accessory and the valve's slit or hole. This can cause damage to the valve that can reduce the efficacy of the endoscope's suction system, and may leak or spray patient debris or fluids, posing an infection control risk.
- When inserting an EndoTherapy accessory, hold it close to the biopsy valve and insert it slowly and straight into the biopsy valve. Otherwise, the EndoTherapy accessory and/or biopsy valve could be damaged. This can reduce the efficacy of the endoscope's suction system, and may leak or spray patient debris or fluids, posing an infection control risk.

CAUTION

When using the aspiration needle (NA series), refer to the instruction manuals for the aspiration needle (NA series). Otherwise, the instrument channel and/or the EndoTherapy accessory may become damaged.

1. Select EndoTherapy accessories compatible with the instrument from the "System chart" in the Appendix. Refer to the accessories' instruction manuals for operating instructions.
2. Move the elevator control lever all the way in the "◀U" direction.
3. Hold the UP/DOWN and RIGHT/LEFT angulation knobs stationary.
4. Confirm that the tip of the EndoTherapy accessory is closed or retracted into its sheath and insert the EndoTherapy accessory slowly and straight into the slit of the biopsy valve.

CAUTION

Do not open the tip of the EndoTherapy accessory or extend the tip of the EndoTherapy accessory from its sheath while the accessory is in the instrument channel. The instrument channel and/or the EndoTherapy accessory may become damaged.

5. Hold the EndoTherapy accessory approximately 4 cm from the biopsy valve and advance it slowly and straight into the biopsy valve using short strokes while observing the endoscopic image.

NOTE

When the tip of the EndoTherapy accessory extends approximately 6 mm from the distal end of the endoscope, the accessory will appear in the endoscopic image, and/or ultrasound image.

6. Hold the EndoTherapy accessory approximately 4 cm from the biopsy valve and advance it slowly and straight into the biopsy valve using short strokes while observing the endoscopic image. Confirm that the tip of the EndoTherapy accessory contacts the forceps elevator.
7. Move the elevator control lever in the opposite direction of the "◀U" direction to lower the forceps elevator. Advance the EndoTherapy accessory slightly and move the elevator control lever in the "◀U" direction confirm that the accessory appears in the endoscopic image.
8. Manipulate the elevator control lever to adjust the height of the elevator (see Figures 4.4 and 4.5).

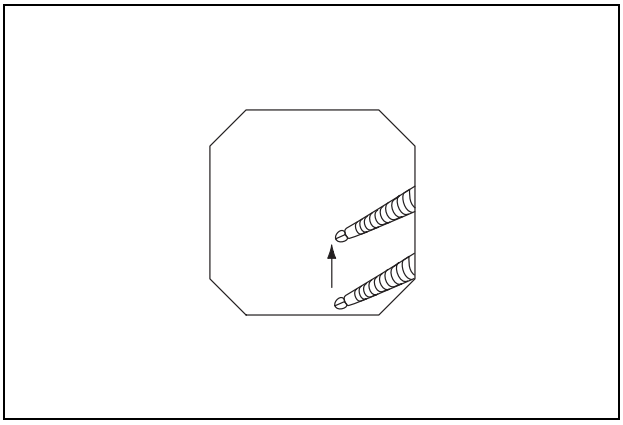


Figure 4.4

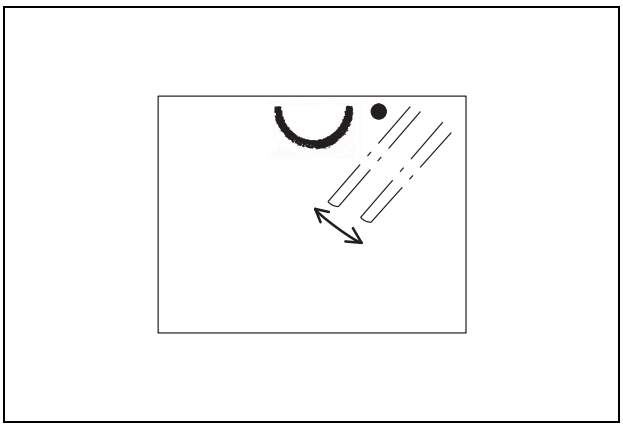


Figure 4.5

Operation of EndoTherapy accessories

Operate the EndoTherapy accessory according to the directions given in its instruction manual.

Withdrawal of EndoTherapy accessories

WARNING

- Patient debris might spray when EndoTherapy accessories are withdrawn from the biopsy valve. To prevent this, hold a piece of gauze around the accessory and the biopsy valve during withdrawal.
- Do not withdraw the EndoTherapy accessory if the tip is open or extended from its sheath; patient injury, bleeding, perforation, and/or instrument damage may occur.
- Withdraw the EndoTherapy accessory slowly and straight out of the biopsy valve. Otherwise, the valve's slit and/or hole could be damaged. This can reduce the efficacy of the endoscope's suction system, and may leak or spray patient debris or fluids, posing an infection control risk.
- If the EndoTherapy accessory cannot be withdrawn from the endoscope, close the EndoTherapy accessory and/or retract it into its sheath, then carefully withdraw both the endoscope and the EndoTherapy accessory together under endoscopic observation. Take care not to cause tissue trauma.

Withdraw the EndoTherapy accessory slowly while the tip of the EndoTherapy accessory is closed and/or retracted into its sheath.

1. Close the tip of the EndoTherapy accessory and/or retract it into its sheath.
2. While lowering the forceps elevator gradually, slowly withdraw the EndoTherapy accessory.

High-frequency cauterization treatment

WARNING

- Performing treatment while the intestines are filled with a flammable gas could result in an explosion, fire, and/or serious patient injury. If the intestines contain a flammable gas, replace it with air or a nonflammable gas such as CO_2 before performing high-frequency treatment.
- Not all parts of the endoscope are electrically insulated. When applying high-frequency current, there is a danger of unintentional diathermy burns. Always wear electrically insulating, chemical-resistant gloves.
- Never emit high-frequency current before confirming that the distal end of the high-frequency EndoTherapy accessory is in the endoscope's field of view. Also, confirm that the electrode section and the mucous membrane in the vicinity of the target area are at an appropriate distance from the distal end of the endoscope. If the high-frequency current is emitted while the distal end of the EndoTherapy accessory is not visible or too close to the distal end of the endoscope, patient injury, bleeding, and/or perforation as well as equipment damage can result.

Prepare, inspect, and connect the electrosurgical unit and electrosurgical accessories as described in their instruction manuals.

NOTE

The application of high-frequency current may interfere with the endoscopic image. This does not indicate a malfunction.

4.4 Withdrawal of the endoscope

WARNING

If blood unexpectedly adheres to the surface of the insertion section of the withdrawn endoscope, carefully check the condition of the patient.

1. When using the balloon method, aspirate water from the balloon by depressing the suction valve while covering the hole in the valve.
2. Freeze the ultrasound image.
3. Aspirate the accumulated air, blood, mucous or other debris by depressing the suction valve to the first stage while covering the hole in the valve.

CAUTION

- Observe the ultrasound image on the video monitor and confirm that the balloon deflates.
- If the balloon does not deflate even when the suction valve is completely depressed, turn OFF the switch of the airflow regulator and remove the air/water valve from the endoscope. In most cases, the balloon will be automatically deflated.
- If the balloon does not deflate even when the air/water valve is removed from the endoscope, tear and deflect the balloon with the EndoTherapy accessory (for example, biopsy forceps).

4. Turn the UP/DOWN and RIGHT/LEFT angulation locks to the “F▶” direction to release them.
5. Carefully withdraw the endoscope while observing the endoscopic image.
6. Remove the mouthpiece from the patient’s mouth.
7. If using the balloon method, detach the balloon.

4.5 Removal of the balloon

CAUTION

- Do not hold the ultrasound transducer when holding the insertion section. The ultrasonic transducer can be damaged, resulting in an abnormal ultrasonic image.
- Do not squeeze the ultrasound transducer forcefully. The ultrasonic transducer can be damaged, resulting in an abnormal ultrasonic image.
- Do not remove the balloon with equipment such as forceps, needle holder, or hemostat that may scratch the surface of the ultrasound transducer. The ultrasonic transducer can be damaged, resulting in an abnormal ultrasonic image.
- Do not pinch the ultrasound transducer surface and balloon together when removing the balloon. The ultrasonic transducer can be damaged, resulting in an abnormal ultrasonic image.

1. Use a clean, lint-free cloth to gently wipe and dry the balloon surface.
2. Roll up the rear end of the balloon with your fingers (see Figure 4.6).
3. After the removal of the balloon, confirm that the surface of the ultrasound transducer is free from scratches. In case the ultrasound transducer surface is scratched, stop using the endoscope and contact Olympus.

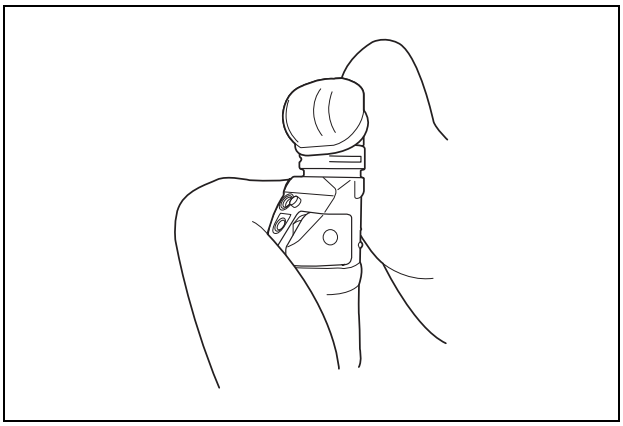


Figure 4.6

4.6 Transportation of the endoscope

Transporting within the hospital

When carrying the endoscope by hand, loop the universal cord, hold the endoscope connector with the control section in one hand and hold the distal end of the insertion tube securely, but gently without squeezing, in the other hand (see Figure 4.7).

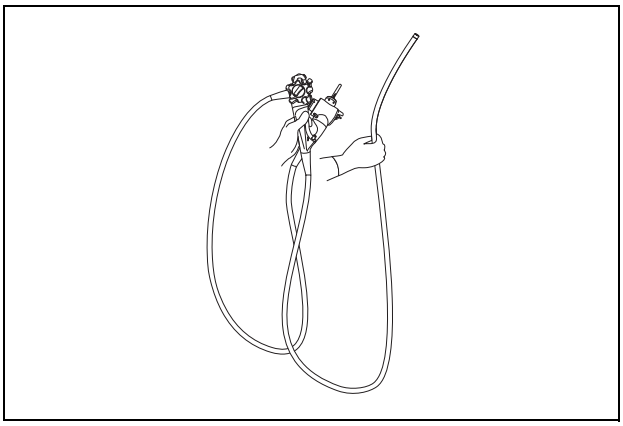


Figure 4.7

Transporting outside the hospital

Transport the endoscope in the carrying case.

WARNING

Always clean, disinfect, or sterilize the endoscope after removing it from the carrying case. If the endoscope is not cleaned, disinfected, or sterilized, it could pose an infection control risk.

CAUTION

- The carrying case cannot be cleaned, disinfected, or sterilized. Clean and disinfect or sterilize the endoscope before placing it in the carrying case.
- To avoid damage to the endoscope caused by changes in air pressure, do not attach the water-resistant cap when transporting the endoscope.
- Before putting the endoscope in the carrying case, always make sure that the forceps elevator is not raised. Putting the endoscope in the carrying case while the forceps elevator is raised could damage the endoscope.

Chapter 5 Reprocessing: General Policy

5.1 Instructions

- Chapters 5, “Reprocessing: General Policy” through 8, “Cleaning and Disinfection Equipment” describe recommended procedures and equipment for cleaning and disinfecting or sterilizing this instrument.
- This instruction manual contains essential information on reprocessing this instrument safely and effectively.
- Before reprocessing, thoroughly review the manuals of the reprocessing chemicals and all equipment that will be used, and reprocess the equipment as instructed.
- Keep this and all related instruction manuals in a safe, accessible location.
- If you have any questions or comments about any information in this manual, or if a problem that cannot be solved occurs while reprocessing, contact Olympus.

5.2 Importance of cleaning, disinfection, and sterilization

The medical literature reports incidents of cross-contamination resulting from improper cleaning, disinfection, or sterilization. It is strongly recommended that all individuals engaged in reprocessing closely observe all instructions given in this manual and the manuals of all ancillary equipment, and have a thorough understanding of the following items:

- Professional health and safety criteria of your hospital
- Individual cleaning, disinfection, and sterilization protocols
- Structure and handling of endoscopic equipment
- Handling of pertinent chemicals

For the types and conditions of the means of cleaning, disinfection, and sterilization to be adopted, please make judgments from your professional viewpoints.

5.3 Precautions

WARNING

- Some endoscope reprocessors are not designed to reprocess an elevator wire channel. If the elevator wire channel cannot be reprocessed by the endoscope reprocessor, clean, disinfect, and sterilize the endoscope according to procedures described in Chapter 7, “Cleaning, Disinfection, and Sterilization Procedures”.
- Failure to properly clean and high-level disinfect or sterilize endoscope equipment after each procedure can compromise patient safety. To minimize the risk of transmitting infectious agents from one patient to another, after each procedure the endoscope and the equipment must undergo thorough manual cleaning followed by high-level disinfection or sterilization, as described in Chapter 7, “Cleaning, Disinfection, and Sterilization Procedures”. Reprocess not only the external surface of the endoscope but also all channels.
- ALL channels of the endoscope, including the elevator wire channel and balloon channel, MUST be cleaned and high-level disinfected or sterilized during EVERY reprocessing cycle, even if the channels were not used during the previous patient procedure. Otherwise, insufficient cleaning and disinfection or sterilization of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope.
- After thoroughly brushing or wiping all external surfaces and the distal end of the endoscope and around the forceps elevator with a soft brush or lint-free cloth, always visually confirm that the elevator wire is not broken. If the elevator wire is broken, patient and/or operator injury could result.
- If the endoscope is not cleaned meticulously, effective disinfection or sterilization may not be possible. Clean the endoscope and accessories thoroughly before disinfection or sterilization to remove microorganisms and organic material that could reduce the efficacy of disinfection or sterilization.
- Olympus only confirms validation of the endoscope reprocessors it recommends. When using an endoscope reprocessor that is not recommended by Olympus, the manufacturer of the endoscope reprocessor is responsible for validating compatibility of the reprocessor with the endoscope models listed in its instruction manual.

- Before using an endoscope reprocessor, confirm that it is capable of reprocessing the endoscope including all channels. If you are uncertain as to the ability of your endoscope reprocessor to clean and high-level disinfect the endoscope including all channels, contact the endoscope reprocessor's manufacturer for specific instructions and/or information on connectors. Insufficient cleaning and disinfection or sterilization of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope.
- Patient debris and reprocessing chemicals are hazardous. Wear personal protective equipment to guard against dangerous chemicals and potentially infectious material. During cleaning and disinfection or sterilization, wear appropriate personal protective equipment, such as eyewear, face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed. Always remove contaminated personal protective equipment before leaving the reprocessing area.
- Thoroughly rinse off the disinfectant solution. Rinse the external surfaces of the endoscope, channels, and cleaning equipment thoroughly with clean water to remove any disinfectant solution residue.
- The disinfection/sterilization room must be adequately ventilated. Adequate ventilation protects against the buildup of toxic chemical fumes.
- Store alcohol in an airtight container. Alcohol stored in an open container is a fire hazard and will lose its efficacy due to evaporation.
- Be sure to perform a leakage test on the endoscope prior to manual cleaning, and do not use the endoscope if a leak is detected. Use of an endoscope with a leak may cause a sudden loss of the endoscopic image, damage to the bending mechanism or other malfunctions.
- Prior to each procedure, confirm that the endoscope has undergone proper cleaning, disinfection, and sterilization. If it is determined that the endoscope has not been properly reprocessed, reprocess it again following the instructions given in this manual.

- With the cleaning, disinfection, and sterilization methods stated in this instruction manual, prions, which are considered to be the pathogenic substance of the Creutzfeldt-Jakob disease (CJD) cannot be destroyed or inactivated. When using this instrument on a patient with CJD or variant Creutzfeldt-Jakob disease (vCJD), be sure to use this product for such patient only and/or immediately dispose of this product after use in an appropriate manner. For methods to handle CJD, please follow the respective guidelines in your country.
- This instrument is not durable, or does not have sufficient durability against the respective methods stated in the guidelines of each country for destroying or inactivating prions. For information on the durability against each method, please contact Olympus. If cleaning, disinfection, and sterilization methods not stated in this instruction manual are performed, Olympus cannot guarantee the effectiveness, safety and durability of this instrument. Make sure to confirm that there is no irregularity before use, and use under responsibility of a physician. Do not use if any irregularity is found.

CAUTION

- When aerating or irrigating the endoscope channels, the air or water pressure must not exceed 0.2 MPa (2 kgf/cm^2, 29 psig). Higher pressures may cause damage to the endoscope.
- When reprocessing an endoscope, confirm that the two water-resistant caps are securely attached to the endoscope connector before immersion in reprocessing fluids. If two water-resistant caps are not securely attached, water, detergent solution and/or disinfectant solution could enter the endoscope and damage the equipment.

5.4 Reprocessing before the first use/reprocessing and storage after use

This instrument was not cleaned, disinfected, or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in this manual.
After using this instrument, reprocess and store it according to the instructions given in this manual. Improper and/or incomplete reprocessing or storage can present an infection control risk, cause equipment damage, or reduce performance.

Chapter 6 Compatible Reprocessing Methods and Chemical Agents

6.1 Compatibility summary

Olympus endoscopic equipment is compatible with several methods of reprocessing. However, certain components and accessories are not compatible with some methods, which can cause equipment damage. For appropriate reprocessing methods, refer to see Table 6.1, the recommendations of your infection control committee and all national and local hospital guidelines and policies.

	Steam sterilization (autoclaving)	Ethylene oxide gas sterilization (gas mixture 20% ethylene oxide gas/80% CO_2 for countries other than the USA)	Ethylene oxide gas sterilization (100% ethylene oxide gas)	ACECIDE disinfectant solution *3 (use OER-A, OER-AW, OER-Pro)	2 – 3.5% glutaraldehyde	70% ethyl or isopropyl alcohol	Detergent solution	Ultrasonic cleaning
Endoscope	*1							
Water-resistant cap (MH-553) Chain for water-resistant cap (MAJ-1739)	*2							
Channel cleaning brush (BW-20T, BW-7L) Channel-opening cleaning brush (MH-507)								
Air/water valve (MAJ-1444) Suction valve (MAJ-1443)								
Channel plug (MAJ-621) Injection tube (MH-946) Air/water channel cleaning adapter (MAJ-629)								

	Steam sterilization (autoclaving)							
	Ethylene oxide gas sterilization (gas mixture 20% ethylene oxide gas/80% CO_2 for countries other than the USA)							
	Ethylene oxide gas sterilization (100% ethylene oxide gas)							
	ACECIDE disinfectant solution *3 (use OER-A, OER-AW, OER-Pro)							
	2 – 3.5% glutaraldehyde							
	70% ethyl or isopropyl alcohol							
	Detergent solution							
	Ultrasonic cleaning							
Suction cleaning adapter (MH-856) Mouthpiece (MB-142) Washing tube (MH-974) Cleaning adapter for instrument channel port (MAJ-350)	■	■	■	■		■	■	■
Biopsy valve (MAJ-853)	■	■	■	■	■	■	■	■
Balloon applicator (MAJ-675)		■	■	■		■	■	
Balloon (MAJ-213)*4			■			■	■	
Cleaning brush (MAJ-1534)	■	■	■	■				■
Balloon 3 (MAJ-249) Single use channel cleaning brush (BW-201T) Single use channel-opening cleaning brush (MAJ-1339)								
Ultrasonic cable (MAJ-1597)			■					

■ compatible □ not compatible

Table 6.1

∗1 The endoscope is compatible with ultrasonic cleaning only when using an endoscope reprocessor such as OER, OER-A, OER-AW and OER-Pro (OER, OER-A, OER-AW and OER-Pro may not be available in some areas).

∗2 The water-resistant caps and the chain for water-resistant caps can only be ultrasonically cleaned if connected to the endoscope that is being cleaned in an endoscope reprocessor with an ultrasonic cleaning phase.

∗3 ACECIDE disinfectant solution is exclusively for an Olympus-recommended endoscope reprocessor such as OER-A, OER-AW and OER-Pro (ACECIDE and Acecide-C may not be available in some areas).

∗4 This item is not available in the USA.

WARNING

Alcohol is not a sterilant or high-level disinfectant.

CAUTION

- The endoscope is not compatible with steam sterilization (autoclaving). Reprocessing using steam sterilization will result in severe equipment damage.
- The ultrasonic cable is not waterproof. Never immerse it in disinfectant solution or any other fluids.

NOTE

- The endoscope is compatible with some endoscope reprocessors such as the ETD[∗1] system distributed by Olympus. Refer to the respective instruction manual for details on operation. For any other details, please contact Olympus.

  ∗1 This product may not be available in some areas.

- EndoTherapy accessories that are marked by the words “AUTOCLAVE” or “AUTOCLAVABLE”, or accessories with a green model reference label are compatible with steam sterilization (autoclaving).

6.2 Detergent solution

Use a medical-grade, low-foaming, neutral pH detergent or enzymatic detergent and follow the manufacturer’s dilution and temperature recommendations. Contact Olympus for the names of specific brands that have been tested for compatibility with the endoscope. Do not reuse detergent solutions.

WARNING

Excessive detergent foaming can prevent fluid from adequately contacting internal lumens (e.g., channels).

6.3 Disinfectant solution

In the U.S., agents used to achieve high-level disinfection are defined as liquid chemical germicides registered with the U.S. Food and Drug Administration as “sterilant/disinfectants” that are used according to the time, temperature and dilution recommended by the disinfectant manufacturer for achieving high-level disinfection. These conditions usually coincide with those recommended by the disinfectant manufacturer for 100% kill of mycobacterium tuberculosis.

In general, 2.0 – 3.5% glutaraldehyde solutions, when used according to the manufacturer’s instructions for achieving high-level disinfection, are compatible with Olympus endoscopes. Contact Olympus for the names of specific brands that have been tested for compatibility with this endoscope.

If disinfectant solution is reused, routinely check its efficacy according to the manufacturer’s recommendations. Do not use solutions beyond their expiration date.

WARNING

Alcohol is not a sterilant or high-level disinfectant.

6.4 Rinse water

Once removed from disinfectant solution, the instrument must be thoroughly rinsed with sterile water to remove any disinfectant residue. If sterile water is not available, clean, potable tap water or water that has been processed (e.g., filtered) to improve its microbiological quality may be used.

When nonsterile water is used after disinfection, wipe the endoscope and flush the channels with 70% ethyl or isopropyl alcohol, then air-dry all internal channels to inhibit the growth of residual bacteria. Do not reuse rinse water.

6.5 Ethylene oxide gas sterilization

This instrument and other accessories listed as compatible with ethylene oxide gas sterilization in Table 6.1 on page 82 can be sterilized by ethylene oxide gas and aerated within the parameters given in Tables 6.2 and 6.3. When performing ethylene oxide gas sterilization, follow the cleaning, disinfection, and sterilization protocols of your hospital and the instruction manuals of the sterilization equipment.

WARNING

- Before sterilization, the instrument must be thoroughly cleaned and dried. Residual moisture may inhibit sterilization.
- The results of sterilization depend on various factors such as how the sterilized instrument was packed or the positioning, method of placing and loading of the instrument in the sterilization device. Please verify the sterilization effects by using biological or chemical indicators. Also follow the guidelines for sterilization issued by medical administrative authorities, public organizations or the infection management sections at each medical facility, as well as the instruction manual for the sterilization device.
- All instruments must be properly aerated following ethylene oxide gas sterilization to remove toxic ethylene oxide residuals.

CAUTION

- Exceeding the recommended parameters may cause equipment damage (see Tables 6.2 and 6.3).
- Disconnect the water-resistant caps from the endoscope connector before ethylene oxide gas sterilization. If the water-resistant cap is attached during ethylene oxide gas sterilization, the air inside the endoscope will expand and rupture the covering of the bending section and/or damage the angulation mechanism.

❍ Parameters for 100% ethylene oxide gas sterilization cycles

Process phase	Parameter	Value
Sterilization	**Temperature**	55°C (130°F)
	Vacuum (Absolute pressure)	0.05 – 0.07 MPa (7.25 – 10.15 psia)
	Relative humidity	50 – 80%
	Ethylene oxide gas concentration	0.735 – 0.740 mg/cm^3 (735 – 740 mg/L)
	Exposure time	60 minutes
Aeration	**Minimum aeration parameters**	12 hours in an aeration chamber at 50 – 57°C (122 – 135°F) or 7 days at room temperature

Table 6.2

❍ Parameters for 20% ethylene oxide gas/80% CO_2 gas sterilization cycles, for countries other than the USA

Process phase	Parameter	Value
Sterilization	**Temperature**	57°C (135°F)
	Relative pressure	0.1 – 0.17 MPa
	Relative humidity	55%
	Ethylene oxide gas concentration	0.6 – 0.7 mg/cm^3 (600 – 700 mg/L)
	Exposure time	105 minutes
Aeration	**Minimum aeration parameters**	12 hours in an aeration chamber at 50 – 57°C (122 – 135°F) or 7 days at room temperature

Table 6.3

6.6 Steam sterilization (autoclaving) of accessories

The accessories listed as compatible with steam sterilization (autoclaving) in Table 6.1 on page 82 can be sterilized by steam within the parameters given in Table 6.4. When steam sterilizing, follow the cleaning, disinfection, and sterilization protocols of your hospital as well as the instructions provided by the manufacturer of your sterilization equipment.

WARNING

The results of sterilization depend on various factors such as how the sterilized instrument was packed or the positioning, method of placing and loading of the instrument in the sterilization device. Please verify the sterilization effects by using biological or chemical indicators. Also follow the guidelines for sterilization issued by medical administrative authorities, public organizations or the infection management sections at each medical facility, as well as the instruction manual for the sterilization device.

CAUTION

- Do not steam sterilize the endoscope. Steam sterilization (autoclaving) will severely damage the endoscope.
- Do not exceed a setting temperature of 134°C (273°F), equivalent to a maximum temperature of 137°C (279°F), nor an exposure time greater than 20 minutes. Otherwise, the accessories may be damaged.

Process	Parameters	
Prevacuum	**Temperature**	132 – 134°C (270 – 274°F)
	Exposure time	5 minutes

Table 6.4 Steam sterilization (autoclaving) exposure parameters

Chapter 7 Cleaning, Disinfection, and Sterilization Procedures

WARNING

ALL channels of the endoscope, including the elevator wire channel and balloon channel, MUST be cleaned and high-level disinfected or sterilized during EVERY reprocessing cycle, even if the channels were not used during the previous patient procedure. Otherwise, insufficient cleaning and disinfection or sterilization of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope.

CAUTION

- Do not coil the endoscope's insertion section or universal cord into a diameter of less than 12 cm. The endoscope can be damaged if coiled too tightly.
- For proper reprocessing results, do not coil the insertion section or universal cord with a diameter of less than 40 cm. If the diameter is less than 40 cm, it will be difficult to insert the channel cleaning brushes (BW-20T, BW-7L), single use single-ended cleaning brush (BW-400L), single use combination cleaning brush (BW-412T) and/or the single use channel cleaning brush (BW-201T).

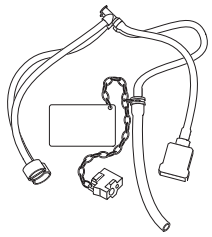
7.1 Required reprocessing equipment

Preparation of the equipment

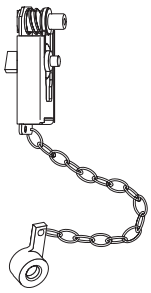
Prior to cleaning and disinfection or sterilization, prepare the equipment shown in Figure 7.1.

CAUTION

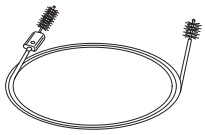
Use basins that are at least 40 cm by 40 cm (16" by 16") in size and deep enough to allow the endoscope to be completely immersed.



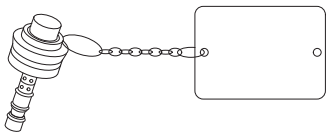
Injection tube (MH-946)



Channel plug (MAJ-621)



Single use combination cleaning brush (BW-412T*1)

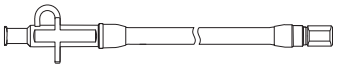


Air/water channel cleaning adapter (MAJ-629)

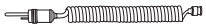
Suction cleaning adapter (MH-856)

Channel cleaning brush (BW-20T) or single use channel cleaning brush (BW-201T*1)

Channel cleaning brush (BW-7L*1) or single use single-ended cleaning brush (BW-400L*1)



Washing tube (MH-974)

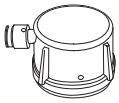


Leakage tester (MB-155)

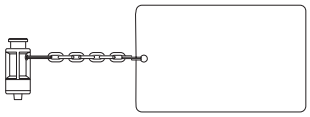
Channel-opening cleaning brush (MH-507) or single use channel-opening cleaning brush (MAJ-1339*1)

Biopsy valve (MAJ-853)

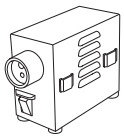
Cleaning brush (MAJ-1534)



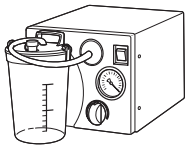
Water-resistant cap (MH-553, 2 pcs)



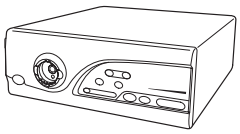
Cleaning adapter for instrument channel port (MAJ-350)



Maintenance unit (MU-1) (sold separately)



Suction pump (KV-4, KV-5, SSU-2) (sold separately)



Light source (sold separately)

*1 These products may not be available in some areas.

• **Detergent solution**	• **Large basin with a tight-fitting lid for detergent and disinfectant solution**	• **Large basins for rinsing**	• **Clean, lint-free cloths**
• **Clean water**	• **Large basin for rinsing and leakage testing**	• **500 cm^3 (500 ml) container**	• **Sterile, cotton swabs**
• **70% ethyl or isopropyl alcohol**	• **Disinfectant solution**	• **30 cm^3 (30 ml) syringe**	• **5 cm^3 (5 ml) syringe**
• **Small containers**	• **Sterile water**	• **Personal protective equipment**	• **Soft-bristled brush**

Figure 7.1

Reprocessing equipment parts and functions

For inspection of other equipment than that mentioned below, refer to the instruction manual for the equipment being used.

❍ Water-resistant cap (MH-553)

The two water-resistant caps are attached to the videoscope cable connector and the ultrasonic cable connector on the endoscope to protect the connectors from water penetration during reprocessing. For leakage testing, the venting connector on the water-resistant cap must be connected to the leakage tester (MB-155) (see Figure 7.2).

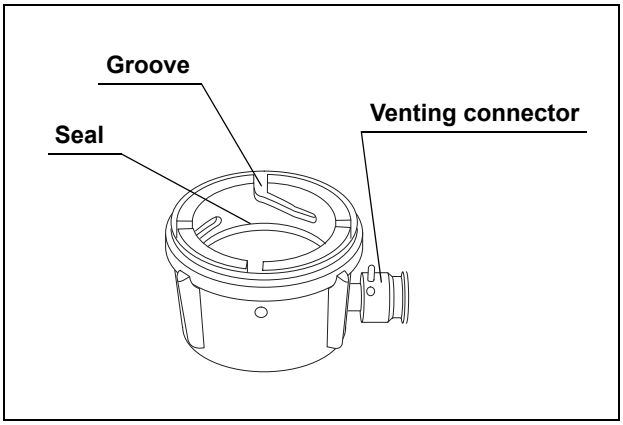


Figure 7.2

❍ Channel cleaning brush (BW-20T, reusable)

The channel cleaning brush is used to brush the inside of the instrument channel, suction channel, and the interior and/or openings of the suction valve, air/water valve, AW channel cleaning adapter, and biopsy valve (see Figure 7.3).

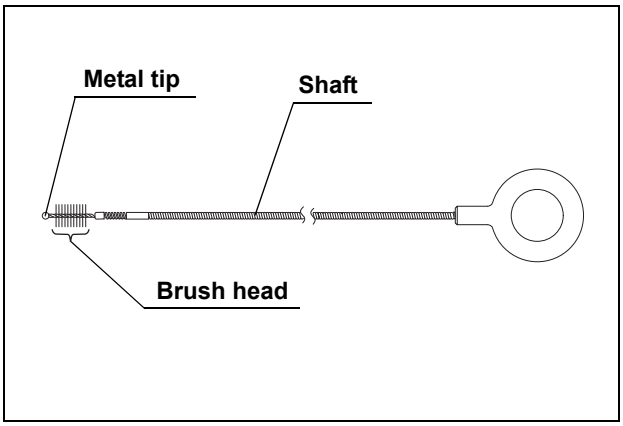


Figure 7.3

❍ Single use channel cleaning brush (BW-201T)

The single use channel cleaning brush is used to brush the inside of the instrument channel, suction channel, and the interior and/or openings of the suction valve, AW channel cleaning adapter, and biopsy valve (see Figure 7.4).

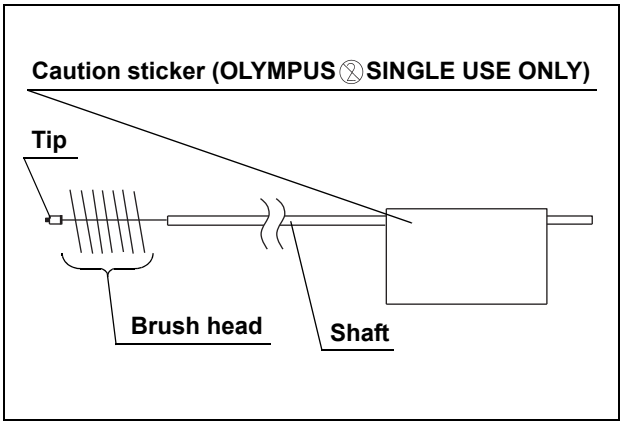


Figure 7.4

❍ Channel cleaning brush (BW-7L/reusable) /Single use single-ended cleaning brush (BW-400L)

The channel cleaning brush or the single use single-ended cleaning brush is used to clean the balloon channel (see Figure 7.5).

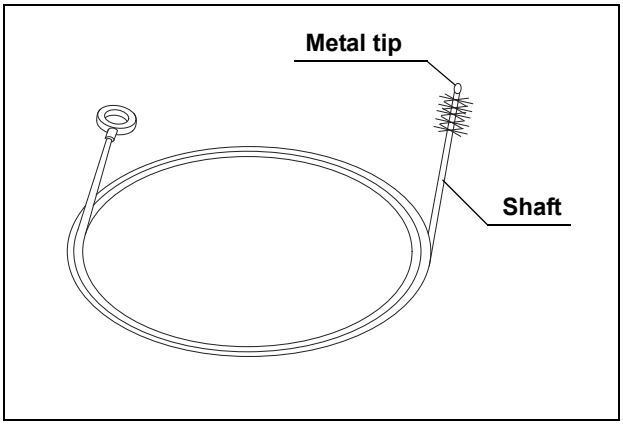


Figure 7.5

❍ Channel-opening cleaning brush (MH-507, reusable)

The channel-opening cleaning brush is used to brush the external surface of the distal end of the endoscope, the suction cylinder, the irrigation port, and the instrument channel port (see Figure 7.6).

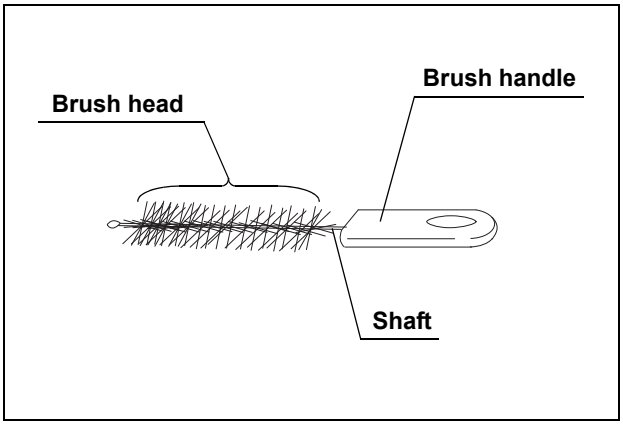


Figure 7.6

❍ Single use channel-opening cleaning brush (MAJ-1339)

The single use channel-opening cleaning brush is used to brush the external surface of the distal end of the endoscope, the suction cylinder, the irrigation port, and the instrument channel port (see Figure 7.7).

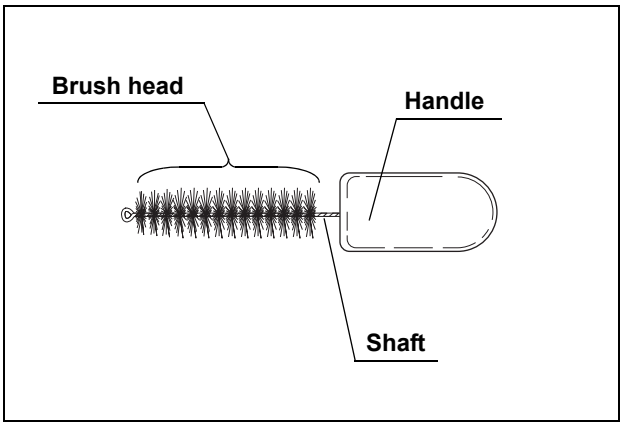


Figure 7.7

❍ Cleaning brush (MAJ-1534)

The cleaning brush is used to brush the external surface of the distal end of the endoscope (see Figure 7.8).

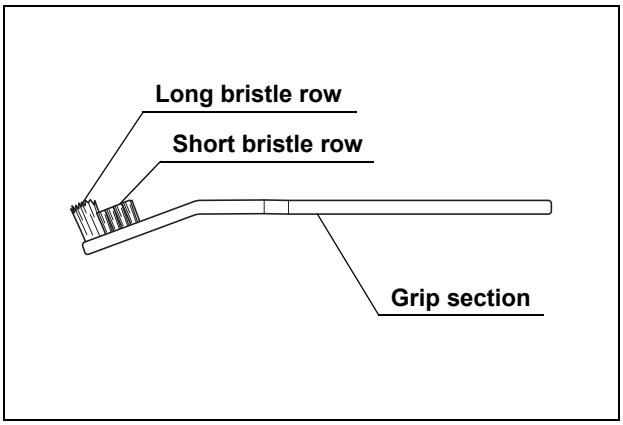


Figure 7.8

❍ Suction cleaning adapter (MH-856)

The suction cleaning adapter is used to aspirate reprocessing fluids from the distal end of the endoscope through the instrument channel (see Figure 7.9).

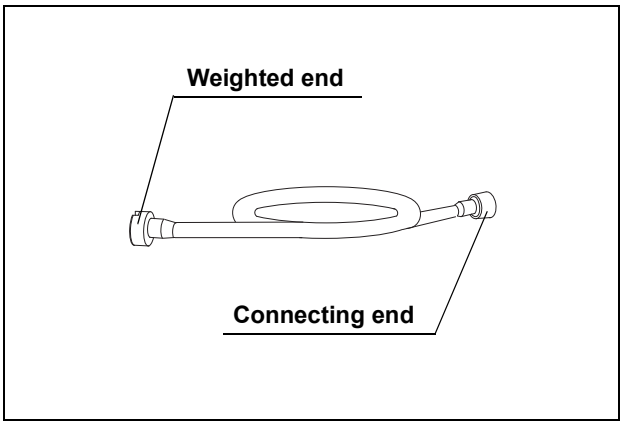


Figure 7.9

❍ Air/water channel cleaning adapter (MAJ-629)

During precleaning, the air/water channel cleaning adapter is connected to the air/water cylinder. When the adapter is depressed, water is fed through the air/water channel. Air is continuously fed when the adapter is not depressed (see Figure 7.10).

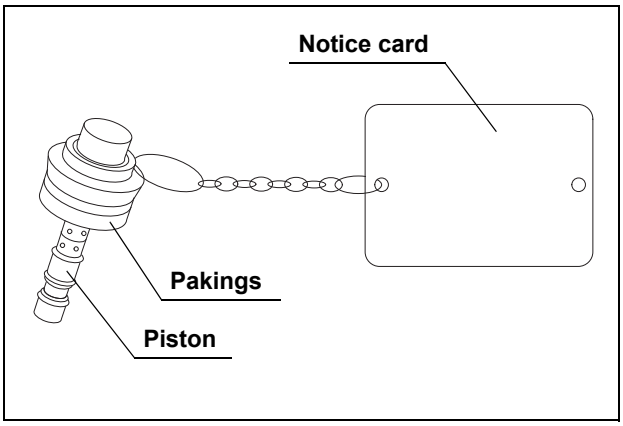


Figure 7.10

WARNING

Use the air/water channel cleaning adapter only during precleaning.

❍ Injection tube (MH-946)

The injection tube is used to inject detergent solution, disinfectant solution, water and alcohol into the air/water channel, instrument channel and suction channel and to flush air through the channels to expel fluids (see Figure 7.11).

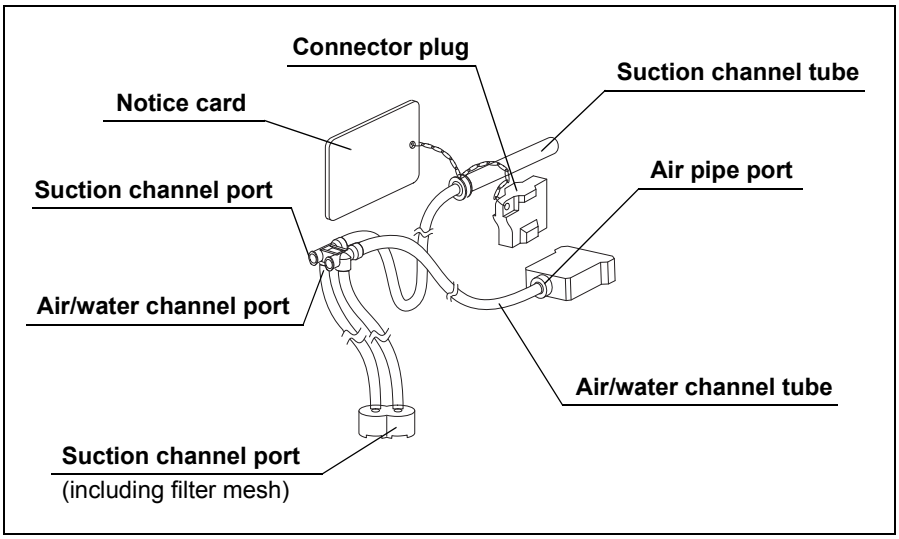


Figure 7.11

❍ Channel plug (MAJ-621)

The channel plug is used to plug the openings of the instrument channel port, air/water and suction cylinders during cleaning (see Figure 7.12).

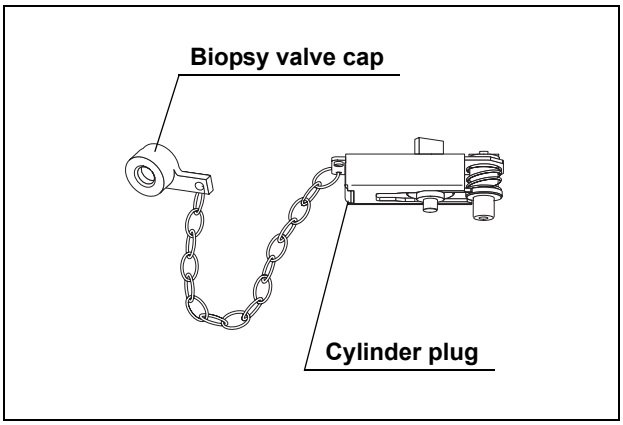


Figure 7.12

❍ Washing tube (MH-974)

The washing tube is used to inject detergent solution, disinfectant solution, water, and alcohol into the elevator wire channel and to flush air through the channel to expel fluids (see Figure 7.13).

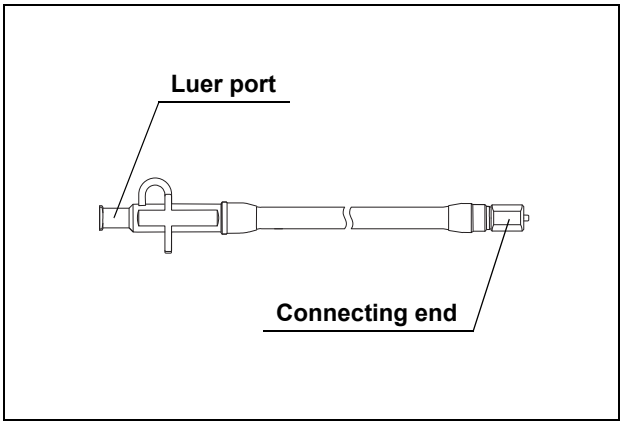


Figure 7.13

❍ Cleaning adapter for instrument channel port (MAJ-350)

The cleaning adapter for instrument channel port is attached to the instrument channel port during reprocessing so that the endoscope may be connected to reprocessing equipment (see Figure 7.14).

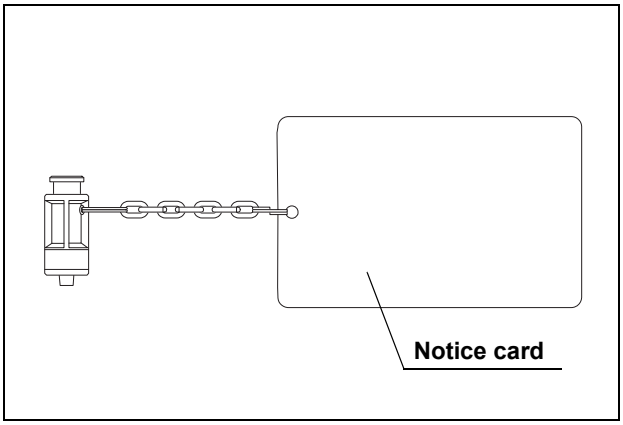


Figure 7.14

❍ Single use combination cleaning brush (BW-412T)

The channel cleaning brush part of the single use combination cleaning brush is used to brush the inside of the instrument channel, suction channel, and the interior and/or openings of the suction valve, AW channel cleaning adapter, and biopsy valve. The channel-opening cleaning brush part of the single use combination cleaning brush is used to brush the external surface of the distal end of the endoscope, the suction cylinder, the irrigation port, and the instrument channel port (see Figure 7.15).

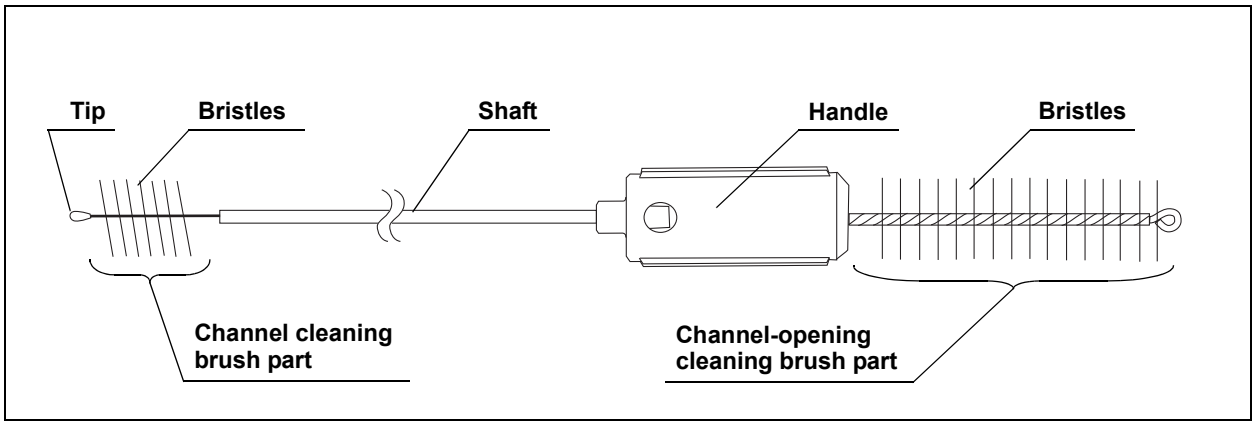


Figure 7.15

Inspection of reusable equipment

For inspection of other equipment than that mentioned below, refer to the instruction manual for the equipment being used.

WARNING

All equipment mentioned below is consumable. Should any irregularity be observed, use a spare instead. Using defective equipment may make it difficult to effectively reprocess the endoscope, and could cause endoscope and/or equipment damage.

CAUTION

Do not immerse the water-resistant cap alone in water. Moisture remaining on the inner side of the cap may penetrate the videoscope cable connector and cause equipment damage.

❍ Inspection of the water-resistant caps (MH-553)

1. Confirm that the inside of the water-resistant caps is dry and free from debris (see Figure 7.2 on page 90). Wipe with a dry cloth when the inside of the water-resistant cap is wet or debris is detected.
2. Confirm that the seal inside the water-resistant cap is free from scratches, flaws, and debris.
3. Check the venting connector for looseness.

❍ Inspection of the suction cleaning adapter (MH-856)

Check for cracks, scratches, flaws, debris and other damage (see Figure 7.9 on page 93).

❍ Inspection of the air/water channel cleaning adapter (MAJ-629)

Check for cracks, scratches, flaws, debris and other damage (see Figure 7.10 on page 94).

Inspection of the injection tube (MH-946)

1. Confirm that all components of the injection tube are free from cracks, scratches, flaws and debris (see Figure 7.11 on page 94).
2. Confirm that the filter mesh is in the suction port.
3. Attach the 30 cm^3 (30 ml) syringe to the air/water channel port. With the filter mesh immersed in rinse water, withdraw the syringe plunger and confirm that rinse water is drawn into the syringe. Depress the plunger and confirm that rinse water is emitted from the air pipe port. Confirm that water is not emitted from the suction port.
4. Attach the 30 cm^3 (30 ml) syringe to the suction channel port. With the filter mesh immersed in rinse water, withdraw the syringe plunger and confirm that rinse water is drawn into the syringe. Depress the plunger and confirm that rinse water is emitted from the distal end of the suction channel tube. Confirm that water is not emitted from the suction port.

Inspection of the channel plug (MAJ-621)

Confirm that the cylinder plug and biopsy valve cap are free from cracks, scratches, flaws and debris (see Figure 7.12 on page 95).

Inspection of the cleaning adapter for instrument channel port (MAJ-350)

Check for cracks, scratches, flaws, debris and other damage (see Figure 7.14 on page 96).

Inspection of the washing tube (MH-974)

Check for cracks, scratches, flaws, debris and other damage (see Figure 7.13 on page 95).

Inspection of the channel cleaning brushes (BW-20T, BW-7L)

1. Confirm that the brush section and the metal tip at the distal end are securely in place. Check for loose or missing bristles (see Figure 7.4 on page 91).
2. Check for bends, scratches and other damage to the shaft.
3. Check for debris on the shaft and/or in the bristles of the brush head.

Inspection of the channel-opening cleaning brush (MH-507)

1. Check the brush head for loose or missing bristles (see Figure 7.6 on page 92).
2. Check for bends, scratches, and other damage to the shaft.
3. Check for debris on the shaft and/or in the bristles of the brush head.

Inspection of the cleaning brush (MAJ-1534)

1. Check the brush head for loose or missing bristles (see Figure 7.8 on page 93).
2. Check the handle for scratches and other damage.

Inspection of single-use equipment

WARNING

- All items mentioned below are single-use items. Do not clean, disinfect, or sterilize the equipment prior to use and/or after use. Doing so may damage the equipment. Using damaged equipment may make it difficult to effectively reprocess the endoscope, and could cause endoscope and/or equipment damage.
- Do not store the equipment outside its packaging. Doing so could allow the equipment to become damaged. Before use, inspect the bristles for any damage. If the bristles are crushed, gently straighten them with your fingers. Using a brush with crushed bristles may make it difficult to effectively reprocess the endoscope.
- Before use, inspect the equipment for any irregularities. Should any irregularity be observed, use a spare instead. Using defective equipment may result in ineffectual reprocessing, and could cause endoscope and/or equipment damage.

Inspection of the single use channel cleaning brush (BW-201T)

1. Remove the packaging immediately before use (see Figure 7.16).
2. Confirm that the tip and bristles at the distal end are securely in place. Check for loose or missing bristles.
3. Check for bends, scratches and other damage to the shaft.
4. Check for debris on the shaft and/or in the bristles of the brush.

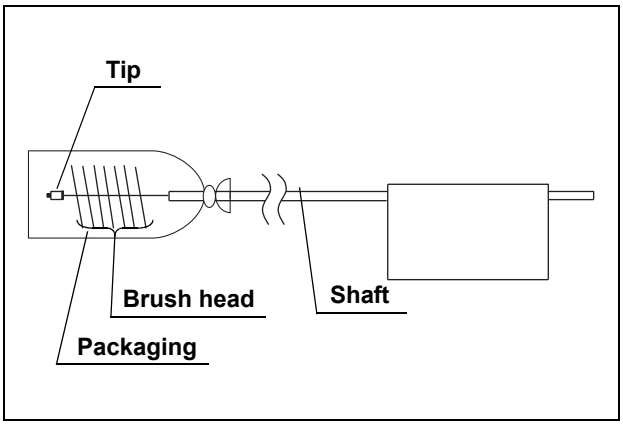


Figure 7.16

Inspection of the single use channel-opening cleaning brush (MAJ-1339)

1. Open the packaging immediately before use (see Figure 7.17).
2. Check for loose or missing bristles.
3. Check for bends, scratches, and other damage to the shaft.
4. Check for debris on the shaft and/or in the bristles of the brush head.

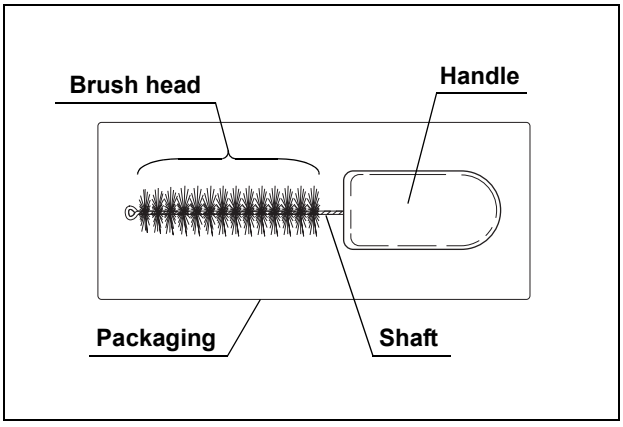


Figure 7.17

Inspection of the single use combination cleaning brush (BW-412T)

1. Remove the brush from its packaging just prior to use (see Figure 7.18).
2. Confirm that the channel cleaning brush part and the tip at the distal end are securely attached.
3. Check the channel cleaning brush and the channel-opening cleaning brush parts for loose or missing bristles.
4. Check the bristles of the channel cleaning brush and the channel-opening cleaning brush parts for any damage. If the bristles are crushed, gently straighten them with your fingertips.
5. Check the shaft for bends, scratches, and other damage. Do not reprocess the single use combination cleaning brush prior to use. The brush may be damaged.

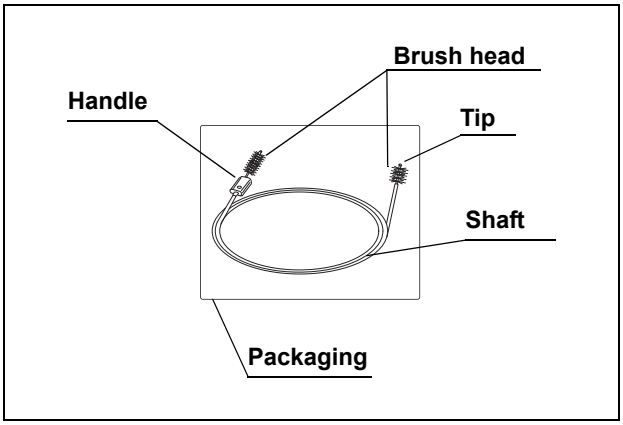
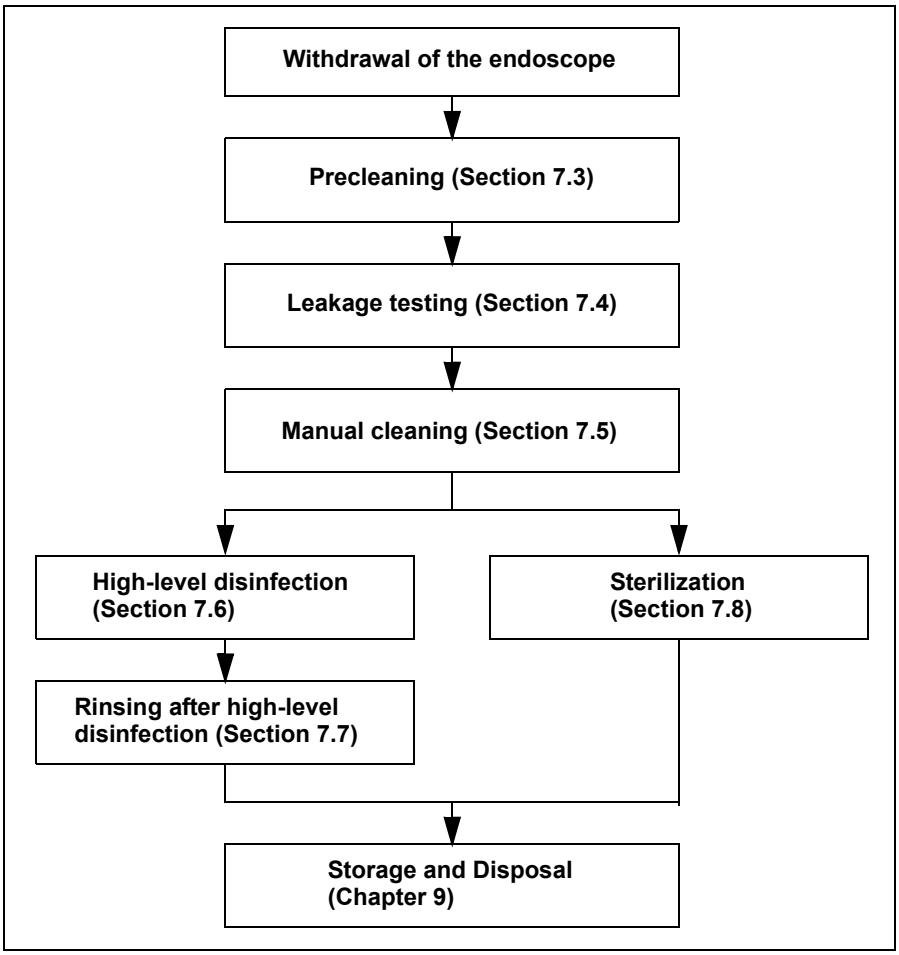


Figure 7.18

7.2 Cleaning, disinfection, and sterilization procedures for the endoscope

After the procedure, clean, disinfect, and sterilize the endoscope according to the procedure described below.

Endoscope reprocessing summary chart


Withdrawal of the endoscope
Precleaning (Section 7.3)
Leakage testing (Section 7.4)
Manual cleaning (Section 7.5)
High-level disinfection (Section 7.6)
Sterilization (Section 7.8)
Rinsing after high-level disinfection (Section 7.7)
Storage and Disposal (Chapter 9)

WARNING

ALL channels of the endoscope, including the elevator wire channel and the balloon channel, MUST be cleaned and high-level disinfected or sterilized during EVERY reprocessing cycle, even if the channels were not used during the previous patient procedure. Otherwise, insufficient cleaning and disinfection or sterilization of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope.

7.3 Precleaning

WARNING

If the endoscope is not immediately precleaned after each procedure, residual organic debris will begin to solidify and it may be difficult to effectively reprocess the endoscope.

Preclean the endoscope at the bedside in the procedure room immediately after each procedure. These steps are to be performed when the suction pump is still connected to the endoscope. During precleaning, wear appropriate personal protective equipment.

Equipment needed

Prepare the following equipment, and wear appropriate protective equipment.

- Personal protective equipment
- Clean, lint-free cloth
- 500 cm^3 (500 ml) containers
- Detergent solution
- Clean water
- Air/water channel cleaning adapter (MAJ-629)
- Washing tube (MH-974)
- 5 cm^3 (5 ml) syringe

Preparation

1. Turn the ultrasound center, video system center and light source OFF.
2. Prepare a 500 cm^3 (500 ml) container of detergent solution at the temperature and concentration recommended by the detergent manufacturer.
3. Prepare clean water in a 500 cm^3 (500 ml) container.

Wipe down the insertion section

CAUTION

- Handle the insertion section carefully. Tightly gripping or sharply bending the insertion section or bending section can stretch or severely damage the insertion section and the covering of the bending section.
- Do not hold the ultrasound transducer when holding the insertion tube. The ultrasound transducer damage can result and/or the ultrasound image will be abnormal.
- Do not squeeze the ultrasound transducer forcefully. The ultrasound transducer damage can result and/or the ultrasound image will be abnormal.

1. Remove and discard the balloon as described in Section 4.5, “Removal of the balloon” on page 74, to ensure proper cleaning of the endoscope.
2. Wipe the entire insertion section with a clean, lint-free cloth soaked in detergent solution. Wipe from the boot at the control section toward the distal end.
3. Gently wipe the ultrasound transducer surface.

Aspirate detergent solution

CAUTION

Monitor the suction bottle on the suction pump carefully to ensure that it does not overflow. Otherwise, suction pump damage could result.

1. Turn the suction pump ON.
2. Attach the biopsy valve cap.
3. Immerse the distal end of the insertion section in detergent solution. Depress the suction valve to the first stage and aspirate detergent solution into the channel for 30 seconds.Then depress the suction valve completely and aspirate detergent solution into the balloon channel for 30 seconds (see Figure 7.19).
4. Remove the distal end of the insertion section from the detergent solution. Depress the suction valve to the first stage and aspirate air for 10 seconds. Then depress the suction valve completely and aspirate air for 10 seconds.
5. Turn the suction pump OFF.

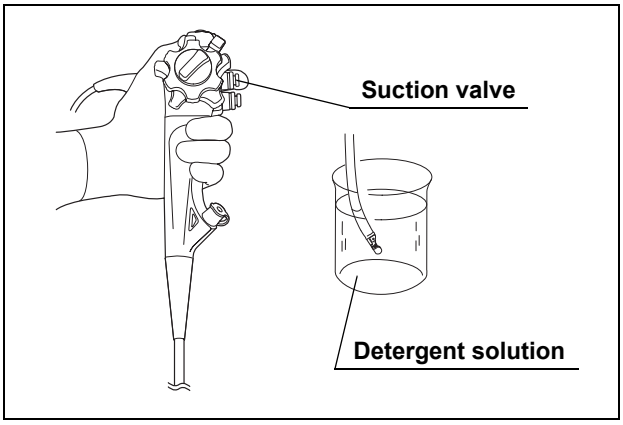


Figure 7.19

Flush water and air into the air/water channel

WARNING

Do not use the air/water channel cleaning adapter for patient examinations. It will cause continuous insufflation and could result in patient injury.

CAUTION

To prevent clogging of the air/water nozzle, always use the air/water channel cleaning adapter to clean the air/water channel after each use.

1. Prepare clean water in a 500 cm^3 (500 ml) container.
2. Turn the light source ON.
3. Depress the air/water valve completely to feed water into the balloon channel and wash away any liquid that remained in the balloon channel.
4. Switch “OFF” the airflow regulator on the light source.
5. Remove the air/water valve from the endoscope and place it in a container of detergent solution (see Figure 7.20).

NOTE

Water may drip from the air/water valve or cylinder when the air/water valve is detached. The water dripping from the air/water valve or cylinder is clean (i.e., sterile water in the water container). If water is dripping from the air/water valve or cylinder, hold the control section higher than the water container during water feeding.

6. Attach the air/water channel cleaning adapter to the air/water cylinder of the endoscope (see Figure 7.20).

7. Switch the airflow regulator to maximum output (“HIGH” or “3”).
8. Immerse the distal end of the insertion tube in the water (see Figure 7.19).
9. Depress the air/water channel cleaning adapter to feed water through the channels for about 30 seconds. Release the adapter to feed air through the channels for 10 seconds or more.
10. Turn the light source, the EVIS video system center and the ultrasound imaging system OFF.

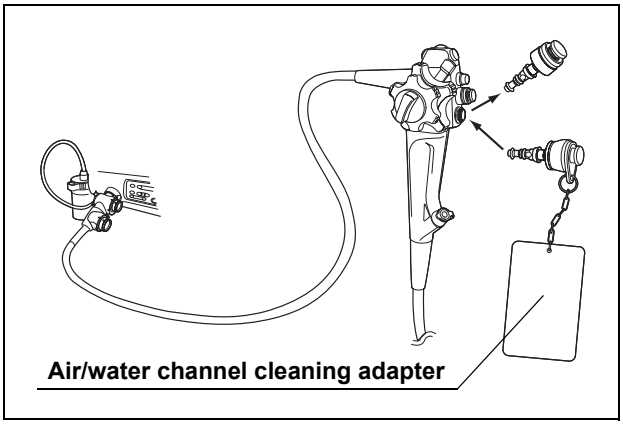


Figure 7.20

Flush detergent solution and air into the elevator wire channel

1. Connect the washing tube to the elevator channel plug (see Figure 7.21).

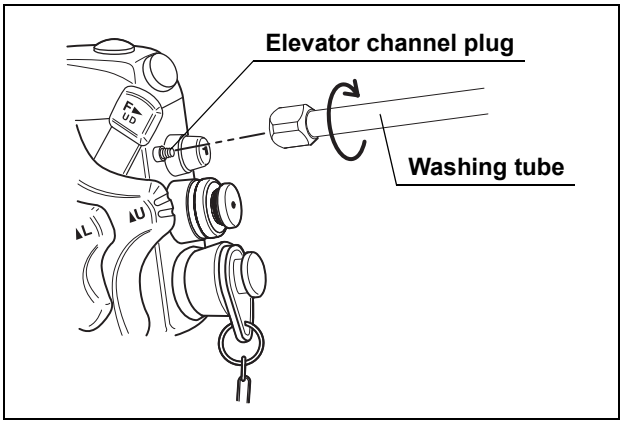


Figure 7.21

2. Immerse the distal end of the insertion section in the clean water.
3. Use the 5 cm^3 (5 ml) syringe, to slowly flush detergent solution through the elevator wire channel several times until no air bubbles exit the distal end (see Figure 7.22).

4. Use the 5 cm^3 (5 ml) syringe to slowly flush clean water through the elevator wire channel several times (see Figure 7.22).
5. Use the 5 cm^3 (5 ml) syringe to slowly flush air through the elevator wire channel several times until a steady stream of air bubbles exit the distal end (see Figure 7.22).

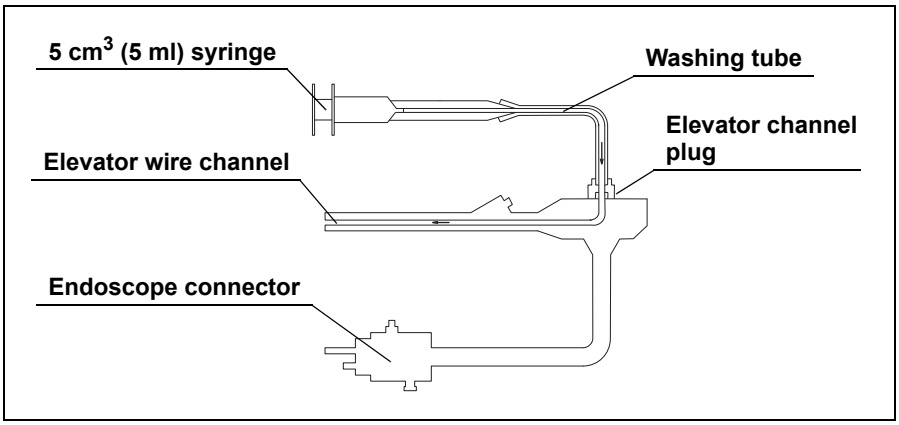


Figure 7.22

Disconnect the endoscope, reusable parts and reprocessing equipment

WARNING

Do not touch the light guide of the endoscope connector immediately after removing it from the light source because it is extremely hot. Operator or patient injury may result.

1. Disconnect the ultrasonic cable from the endoscope's ultrasonic cable connector.
2. Disconnect the videoscope cable from the endoscope's videoscope cable connector.
3. Disconnect the suction tube from the suction connector of the endoscope connector.
4. Disconnect the metal tip of the water container from the air/water supply connector of the endoscope connector. Then, attach the metal tip to the tip receptacle on the lid of the water container as described in the water container's instruction manual.
5. Disconnect the endoscope connector from the light source.
6. Transport the endoscope to the reprocessing area.

7. Detach the air/water channel cleaning adapter, suction valve, and biopsy valve from the endoscope and place them in a container of detergent solution.
8. Disconnect the washing tube from the endoscope.

7.4 Leakage testing

After precleaning, perform leakage testing on the endoscope to ensure that it is waterproof.

Equipment needed

Prepare the following equipment, and wear appropriate personal protective equipment.

- Personal protective equipment
- Large basin
- Clean water
- Maintenance unit or light source (MU-1 or CLV-180, CLV-160, CLV-U40)
- Leakage tester (MB-155)
- Water-resistant cap (2 pcs) (MH-553)

Attaching the water-resistant caps (MH-553)

CAUTION

- The ultrasonic cable connector and the electrical connector of the endoscope are not waterproof. Before immersing or leakage testing the endoscope, always attach the water-resistant caps. Otherwise, equipment damage may result.
- If the exterior of the ultrasonic cable connector and/or the videoscope cable connector is scratched, the connector may no longer be waterproof and the seal inside the water-resistant cap may become scratched. If the ultrasonic cable connector or the electrical connector is scratched, contact Olympus.
- Never immerse the water-resistant caps unless they are attached to the endoscope. Water remaining inside the water-resistant caps can be transferred to and damage the ultrasonic cable connector and/or the videoscope cable connector.

- Always use a dry water-resistant cap. Any water remaining on the water-resistant cap may cause damage to the endoscope, maintenance unit or light source.

1. Confirm that the inside of the water-resistant cap is dry and free from debris. Wipe with a dry, lint-free clean cloth if the inside of the water-resistant cap is wet or there is debris.
2. Align the EW character (see Figures 7.23 (a) and 7.24 (a)) on the water-resistant caps with mark 2 on the electrical connector housing and the ultrasonic cable connector housing. When using a manual disinfector, align the KC/TD character (see Figures 7.23 (b) and 7.24 (b)) on the water-resistant caps with mark 2 on the electrical connector housing and the ultrasonic cable connector housing.
3. Align the pin on the electrical connector and the ultrasonic cable connector with the grooves on the water-resistant caps.
4. Push the water-resistant caps into position and rotate each of them clockwise until they stop (approximately 45°).

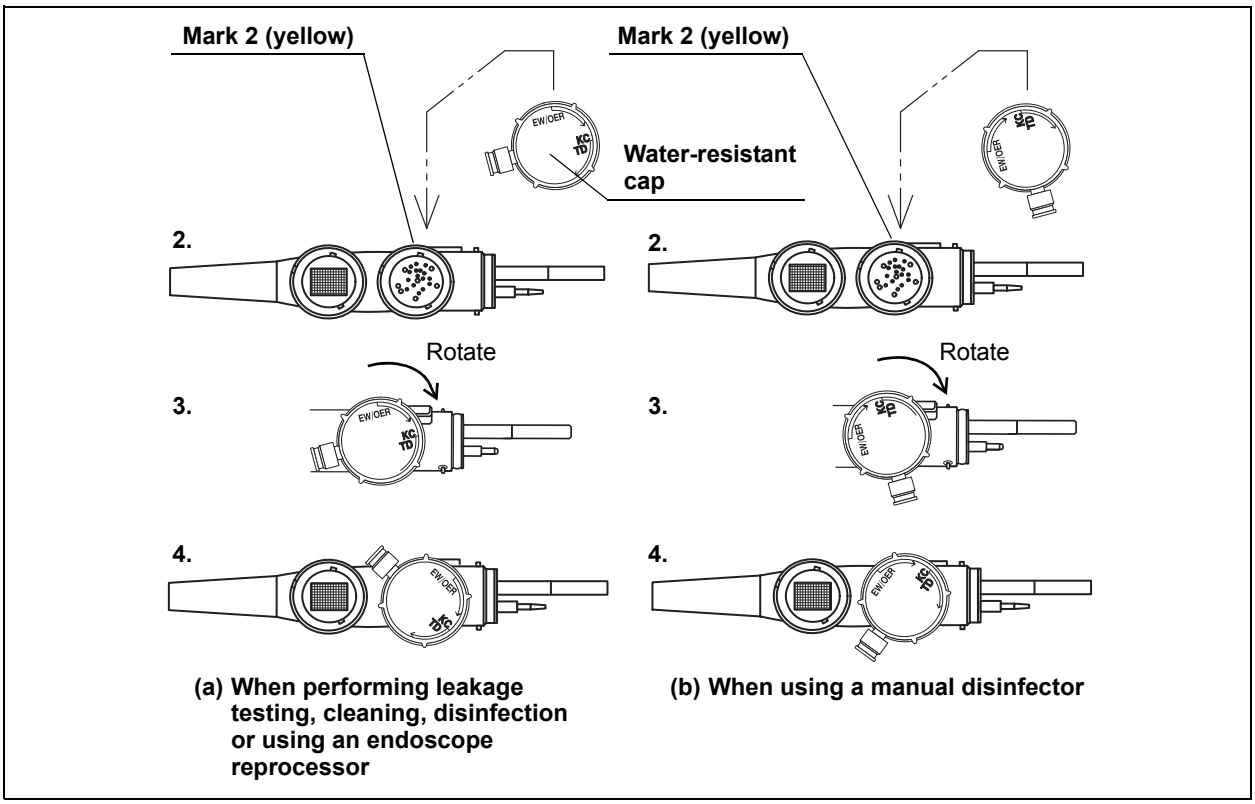


Figure 7.23

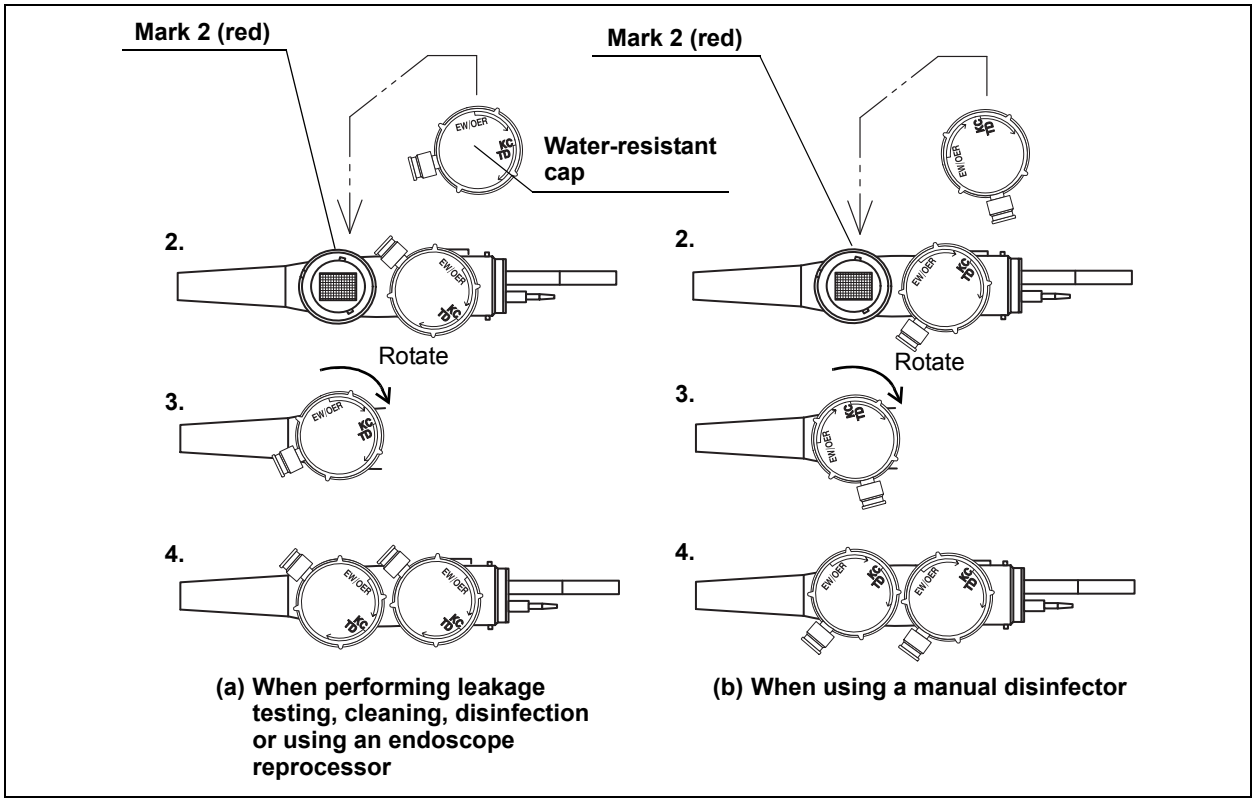

Mark 2 (red)
Water-resistant cap
2.
Rotate
3.
4.
(a) When performing leakage testing, cleaning, disinfection or using an endoscope reprocessor
Mark 2 (red)
2.
Rotate
3.
4.
(b) When using a manual disinfector

Figure 7.24

Performing the leakage test

CAUTION

- During leakage testing, a continuous series of bubbles emerging from a location on the endoscope indicates a leak at that location. This means that water will be able to penetrate the inside of the endoscope. If you locate a leak, remove the endoscope from the water and contact Olympus.
- Never connect or disconnect the water-resistant cap or the leakage tester's connector cap while immersed. Doing so could allow water to enter the endoscope and equipment damage can result.
- Rotate the leakage tester's connector cap until it stops. If it is not fully and properly attached, the endoscope's interior will not be pressurized and accurate leakage testing will be impossible.
- When connecting the leakage tester's connector cap to the water-resistant cap's venting connector, make sure that the inside of the leakage tester's connector cap and the outside of the water-resistant cap's venting connector are completely wiped and dry. Water remaining on either component may penetrate the inside of the water-resistant cap and could cause endoscope malfunction.

NOTE

When the leakage tester connector is in place, the covering of the bending section will expand as the air pressure inside the endoscope increases. This is normal.

1. Fill a basin with clean water. Use a basin that is at least 40 cm by 40 cm (16" by 16") in size and deep enough to allow the endoscope to be completely immersed.
2. Insert the leakage tester connector into the output socket of the maintenance unit or the light source (see Figure 7.25) and turn the maintenance unit or the light source ON. Set the light source's airflow regulator switch to its maximum level.

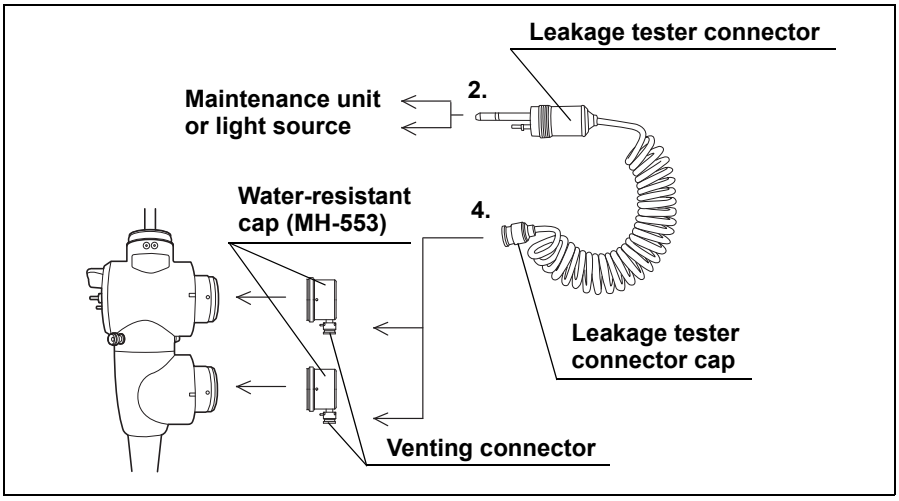


Figure 7.25

3. Confirm that the leakage tester is emitting air by gently depressing the pin located inside the leakage tester's connector cap.
4. Connect the leakage tester's connector cap to either one of the two venting connectors that are in the water-resistant caps of the video cable connector and the ultrasonic cable connector (see Figure 7.25).
5. With the leakage tester connected, immerse the entire endoscope in water and observe for approximately 30 seconds while angulating the bending section. Confirm that there is no location on the endoscope from that a continuous series of bubbles emerges.
6. Remove the endoscope from the basin with the leakage tester attached.
7. Turn the maintenance unit or the light source OFF.
8. Disconnect the leakage tester from the maintenance unit or the light source.

CAUTION

Always disconnect the leakage tester connector from the light source or maintenance unit before disconnecting the leakage tester's connector cap from the venting connector. Failure to do this will not allow the endoscope to depressurize properly. This may damage the endoscope.

9. Wait 30 seconds, or until the covering of the bending section contracts to its pre-expansion size. Disconnect the leakage tester's connector cap from the venting connector.
10. Thoroughly dry the leakage tester.

7.5 Manual cleaning

CAUTION

To prevent a water leak, do not apply excessive force when cleaning the endoscope.

After completing the leakage test, perform manual cleaning according to the procedures described below.

In case of excessive bleeding and/or delayed reprocessing, perform "Presoak for excessive bleeding and/or delayed reprocessing after each procedure" on page 131 and follow the procedure described below.

Reusable parts that are normally reprocessed with the endoscope

- Channel plug (MAJ-621)
- Injection tube (MH-946)
- Water-resistant cap (2 pcs) (MH-553)
- Chain for water-resistance caps (MAJ-1739)
- Washing tube (MH-974)
- Cleaning adapter for instrument channel port (MAJ-350)

Equipment needed

Prepare the following equipment and wear appropriate personal protective equipment.

- Personal protective equipment
- Soft brush
- 30 cm^3 (30 ml) syringe
- Clean, lint-free cloths
- Large basins
- Detergent solution
- Clean water
- Suction pump
- Suction cleaning adapter (MH-856)
- Channel cleaning brush (BW-20T),
  Single use channel cleaning brush (BW-201T) or
  Single use combination cleaning brush (BW-412T)

- Channel-opening cleaning brush (MH-507),
  Single use channel-opening cleaning brush (MAJ-1339) or
  Single use combination cleaning brush (BW-412T)
- Channel cleaning brush (BW-7L)
- Cleaning brush (MAJ-1534)
- Single use single-ended cleaning brush (BW-400L)
- Channel plug (MAJ-621)
- Injection tube (MH-946)
- Cleaning adapter for instrument channel port (MAJ-350)
- Washing tube (MH-974)
- 5 cm^3 (5 ml) syringe

CAUTION

- To prevent damage to the endoscope, never immerse it together with objects other than the equipment listed above.
- Reuse of detergent may cross-contaminate equipment and compromise the safety of personnel cleaning the endoscope. Do not reuse detergent.

Preparation

1. Fill a basin with fresh detergent solution at the temperature and concentration recommended by the detergent manufacturer. Use a basin that is at least 40 cm by 40 cm (16” by 16”) in size and deep enough to completely immerse the endoscope.
2. Fill a basin with clean water. Use a basin that is at least 40 cm by 40 cm (16” by 16”) in size and deep enough to completely immerse the endoscope.

Cleaning the external surface

WARNING

After thoroughly brushing or wiping all external surfaces and the distal end of the endoscope with a soft brush or lint-free cloth, always visually confirm that the elevator wire is not broken. If the elevator wire is broken, patient and/or operator injury could result.

CAUTION

Do not wipe the ultrasonic transducer forcefully. The ultrasonic transducer damage can result and/or the ultrasonic image will be abnormal.

1. Immerse the endoscope in the detergent solution.
2. With the endoscope immersed, use a soft brush or lint-free cloth to thoroughly brush or wipe all external surfaces of the endoscope. Pay particular attention to the air/water nozzle opening and the objective lens, and ensure that all surfaces of the distal end are thoroughly cleaned (see Figure 7.26).

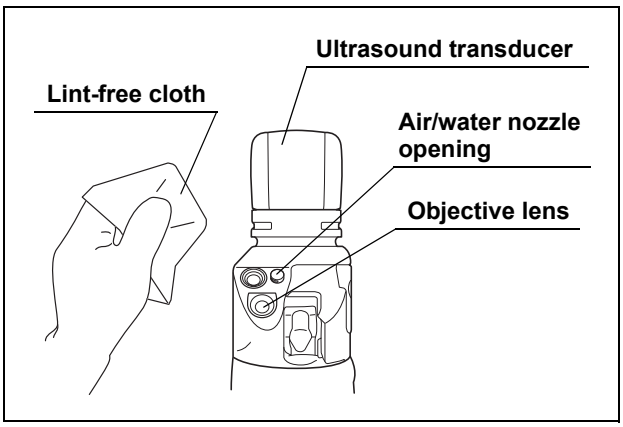


Figure 7.26

Brushing around the forceps elevator and instrument channel outlet

WARNING

- After thoroughly brushing around the forceps elevator with a soft brush, always visually confirm that the elevator wire is not broken. If the elevator wire is broken, patient and/or operator injury could result.
- To avoid splattering detergent solution while brushing, keep the endoscope submerged.

CAUTION

Using a stiff brush or excessive force when brushing may scratch the distal end and result in water leakage, cause the elevator wire to come off the distal end, bend or kink the elevator wire so that the forceps elevator will no longer work.

1. Turn the elevator control lever all the way in the opposite direction of the "◀U" direction. perform the following brushing in the detergent solution.
2. While holding the distal end, brush the groove of the interior of the forceps elevator with the cleaning brush (MAJ-1534) until all debris is removed (see Figure 7.27).

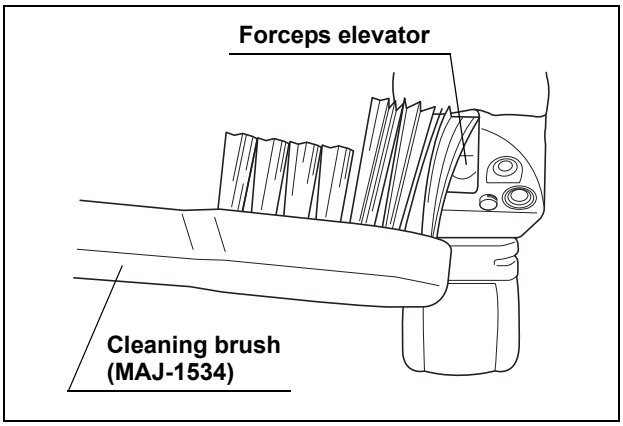


Figure 7.27

3. Look at the left side of the instrument channel opening from the distal end, brush the interior of this part with the cleaning brush (MAJ-1534) until all debris is removed (see Figure 7.28).

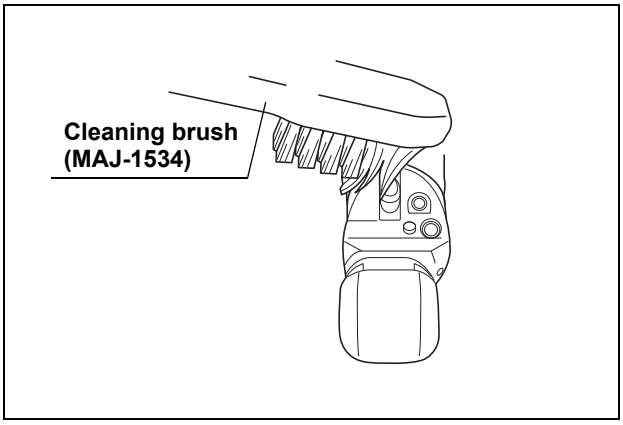


Figure 7.28

4. Look at the right side of the instrument channel opening from the distal end, brush the interior of this part with the cleaning brush (MAJ-1534) until all debris is removed (see Figure 7.29).

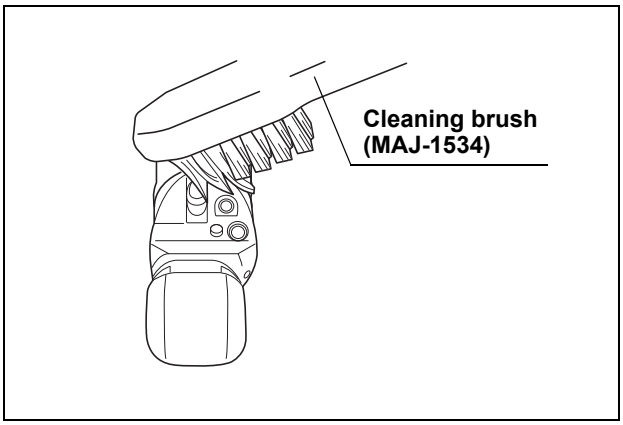


Figure 7.29

5. Move the elevator control lever in the "◀U" direction to raise the forceps elevator.

6. While holding the distal end, brush both sides of the forceps elevator and the opposite side of the groove of the forceps elevator with the cleaning brush (MAJ-1534) until all debris is removed (see Figure 7.30).

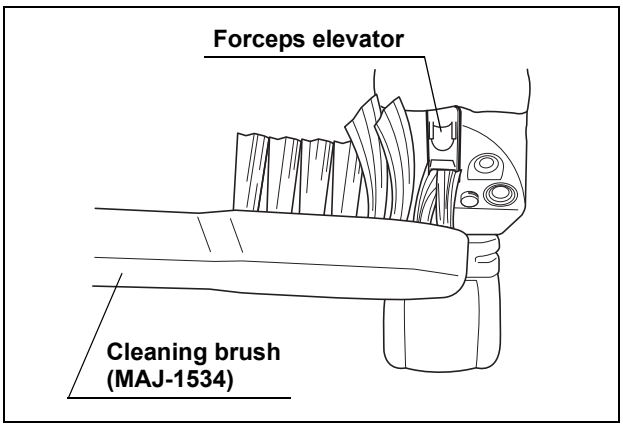


Figure 7.30

7. Brush the distal end of the endoscope, using the cleaning brush (MAJ-1534).

8. Move the elevator control lever all the way in the opposite direction of the "◀U" direction to lower the forceps elevator.

Flushing the interior of the forceps elevator

1. Immerse the distal end in detergent solution, operate the elevator control lever to raise and lower the forceps elevator 3 times.
2. With the forceps elevator raised, flush the interior of the forceps elevator with detergent solution using the 30 cm^3 (30 ml) syringe (see Figure 7.31).

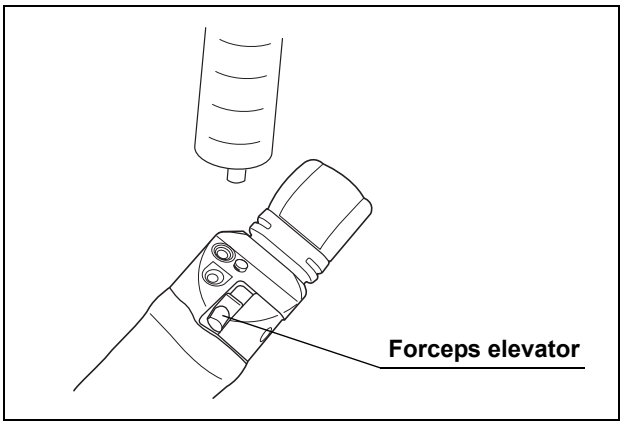


Figure 7.31

Brushing the channels

WARNING

- Be sure to brush the inside of the instrument channel and suction channel. Otherwise, insufficient cleaning and/or disinfection of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope.
- To avoid splattering detergent solution when the channel cleaning brush (BW-20T), the single use channel cleaning brush (BW-201T), or the single use combination cleaning brush (BW-412T) is pulled out, keep the endoscope submerged.

WARNING

- The channel cleaning brush (BW-20T) is a consumable. The single use channel cleaning brush (BW-201T) and the single use combination cleaning brush (BW-412T) are single-use items. Repeated use may cause the brush head to become bent or kinked, which could cause it to come off during use. Confirm that the channel cleaning brush (BW-20T), the single use channel cleaning brush (BW-201T), or the single use combination cleaning brush (BW-412T) is free from any damage or other irregularities before and after use. If a part of the brush comes off inside the endoscope, immediately retrieve it and carefully confirm that no parts remain inside the channel of the endoscope by passing a new cleaning brush or other EndoTherapy accessory through the channel. Any parts left in the channel can drop into the patient during the procedure.
  Depending on the location, the missing part may not be recoverable by passing a new brush or other EndoTherapy accessory through the channel. In this case, contact Olympus.
- Clean only one endoscope and/or accessories with a single use channel cleaning brush (BW-201T), a single use channel-opening cleaning brush (MAJ-1339), a single use combination cleaning brush (BW-412T), a single use single-ended cleaning brush (BW-400L) and dispose of the brushes immediately after use. Using a single use channel cleaning brush (BW-201T), a single use channel-opening cleaning brush (MAJ-1339), a single use combination cleaning brush (BW-412T), a single use single-ended cleaning brush (BW-400L) on more than one endoscope and/or accessories may make it difficult to effectively reprocess the endoscope and/or accessories, and could cause endoscope, accessories and/or equipment damage.

CAUTION

- Gently withdraw the channel cleaning brush (BW-20T), the single use channel cleaning brush (BW-201T), the single use combination cleaning brush (BW-412T), or the single use single-ended cleaning brush (BW-400L) from the instrument channel or suction channel. Make sure that the shaft does not rub against the external opening of the suction cylinder. This could damage the brush and/or wear a groove in the opening, leading to impaired suction and liquid leakage.

CAUTION

- Do not attempt to pass the channel cleaning brush (BW-20T), the single use channel cleaning brush (BW-201T), the single use combination cleaning brush (BW-412T), or the single use single-ended cleaning brush (BW-400L) from the distal end of the insertion section and/or suction connector. It may get caught, making retrieval impossible.

While the endoscope is submerged, brush the instrument and the suction channel, suction cylinder, instrument channel port, balloon channel and irrigation port according to the following procedures (see Figure 7.32).

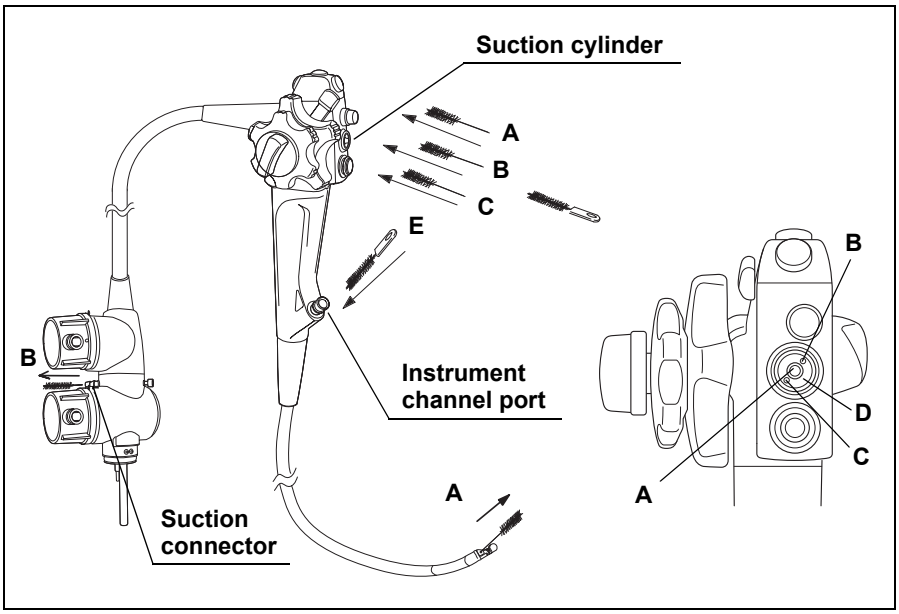


Figure 7.32

❍ Brushing the instrument channel in the insertion tube and suction channel in the control section (location A)

1. Immerse the endoscope in the detergent solution to avoid splattering.
2. Straighten the endoscope's bending section. Grip the channel cleaning brush (BW-20T), the single use channel cleaning brush (BW-201T), or the single use combination cleaning brush (BW-412T) at a point 3 cm from the bristles.
3. Insert the channel cleaning brush (BW-20T), the single use channel cleaning brush (BW-201T), or the single use combination cleaning brush (BW-412T) into the center opening of the suction cylinder as illustrated by A in Figure 7.32. Using short strokes, feed the brush through the insertion tube until it emerges from the distal end of the endoscope.

4. Clean the bristles with your fingertips in the detergent solution. Carefully pull the brush out through the channel and back out of the suction cylinder.
5. Clean the bristles in the detergent solution again.
6. Repeat until all debris is removed.

Brushing the suction channel in the universal cord (location B)

1. Grip the channel cleaning brush (BW-20T), the single use channel cleaning brush (BW-201T), or the single use combination cleaning brush (BW-412T) at a point 3 cm from the bristles.
2. Insert the channel cleaning brush (BW-20T), the single use channel cleaning brush (BW-201T), or the single use combination cleaning brush (BW-412T) straight into the opening of the suction cylinder as illustrated by B in Figure 7.32. Using short strokes, feed the brush through the universal cord until it emerges from the suction connector on the endoscope connector.
3. Clean the bristles with your fingertips in the detergent solution. Carefully pull the brush out through the channel and back out of the suction cylinder.
4. Clean the bristles in the detergent solution again.
5. Repeat until all debris is removed.

Brushing the balloon channel (location C)

1. Grip the channel cleaning brush (BW-7L) or the single use single-ended cleaning brush (BW-400L) at a point 3 cm from the bristles.
2. Insert the channel cleaning brush (BW-7L) or the single use single-ended cleaning brush (BW-400L) straight into the opening of the suction cylinder as illustrated by C in Figure 7.32. Using short strokes, feed the brush until it reaches the distal end near the balloon attachment groove.
   It can be confirmed whether the brush has reached the distal end by looking at the tip of brush through the groove of the balloon water suction port (Rough standard of brush insertion length: 150 cm from point).
3. Pull the brush out through the channel and clean the bristles with your fingertips in the detergent solution.
4. Repeat until all debris is removed.

❍ Brushing the suction cylinder (location D)

CAUTION

When inserting the channel-opening cleaning brush (MH-507), the single use channel-opening cleaning brush (MAJ-1339), or the single use combination cleaning brush (BW-412T) into the suction cylinder, do not forcibly insert the brush beyond the middle of the brush section. Otherwise, the brush may become stuck in the suction cylinder.

1. Insert the channel-opening cleaning brush (MH-507), the single use channel-opening cleaning brush (MAJ-1339), or the single use combination cleaning brush (BW-412T) into the suction cylinder as illustrated by D in Figure 7.32 on page 120 until half of the brush section is inserted.
2. Turn the inserted brush once.
3. Pull the brush out and clean the bristles with your fingertips in the detergent solution.
4. Repeat until all debris is removed.

❍ Brushing the instrument channel port (location E)

1. Insert the channel-opening cleaning brush (MH-507), the single use channel-opening cleaning brush (MAJ-1339), or the single use combination cleaning brush (BW-412T) into the instrument channel port until the brush handle touches the channel opening as illustrated by E in Figure 7.32 on page 120.
2. Turn the inserted brush once.
3. Pull the brush out and clean the bristles with your fingertips in the detergent solution.
4. Repeat until all debris is removed.
5. Insert the channel-opening cleaning brush into the other instrument channel port and repeat Steps 1 through 3 until all debris is removed.
6. Reprocess the channel-opening cleaning brush (MH-507) as described in Section 7.9, “Cleaning, disinfection, and sterilization procedures for reusable parts and reprocessing equipment” on page 139.
7. Dispose of the single use channel-opening cleaning brush (MAJ-1339) or the single use combination cleaning brush (BW-412T) in an appropriate manner.

WARNING

If the single use channel-opening cleaning brush is not properly disposed of, it could pose a risk of contamination and/or infection.

NOTE

The channel cleaning brush (BW-20T) or the single use channel cleaning brush (BW-201T) are used to brush the accessories of the endoscope as described in Section 7.9, “Cleaning, disinfection, and sterilization procedures for reusable parts and reprocessing equipment” on page 139.

8. Remove the endoscope from the detergent solution.

Aspirating detergent solution into the instrument channel and the suction channels

1. Attach the suction valve (MAJ-1443) to the suction cylinder of the endoscope.
2. Attach the cleaning adapter for instrument channel port to the instrument channel port.
3. Attach the suction cleaning adapter to the cleaning adapter for instrument channel port (see Figures 7.33 and 7.34).
4. Connect the suction tube from the suction pump to the suction connector on the endoscope. Turn the suction pump ON.
5. Immerse both the endoscope’s distal end and the weighted end of the suction cleaning adapter in the detergent solution.
6. Depress the suction valve to the first stage and aspirate detergent solution for approximately 30 seconds.
7. Remove both the endoscope’s distal end and the weighted end of the suction cleaning adapter from the detergent solution.
8. Depress the suction valve to the first stage and aspirate air for approximately 30 seconds.
9. Immerse the endoscope’s distal end in the detergent solution again.
10. Depress the suction valve completely and aspirate detergent solution for approximately 30 seconds.
11. Remove the endoscope’s distal end from the detergent solution.
12. Depress the suction valve completely and aspirate air for approximately 30 seconds.

13. Turn the suction pump OFF.

14. Disconnect the suction tube and remove the suction valve and the suction cleaning adapter.

15. Reprocess the suction tube, the suction cleaning adapter and suction valve as described in Section 7.9, “Cleaning, disinfection, and sterilization procedures for reusable parts and reprocessing equipment” on page 139.

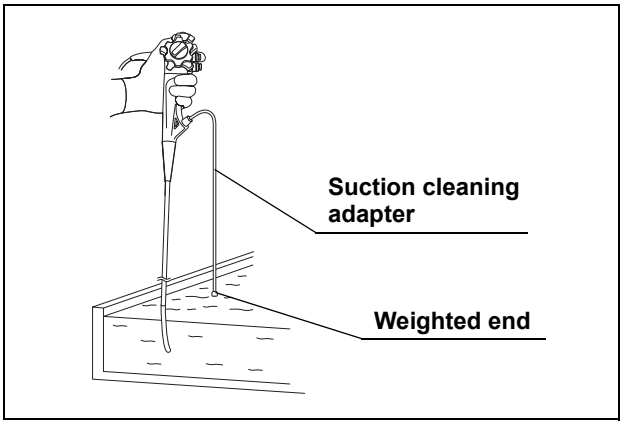


Figure 7.33

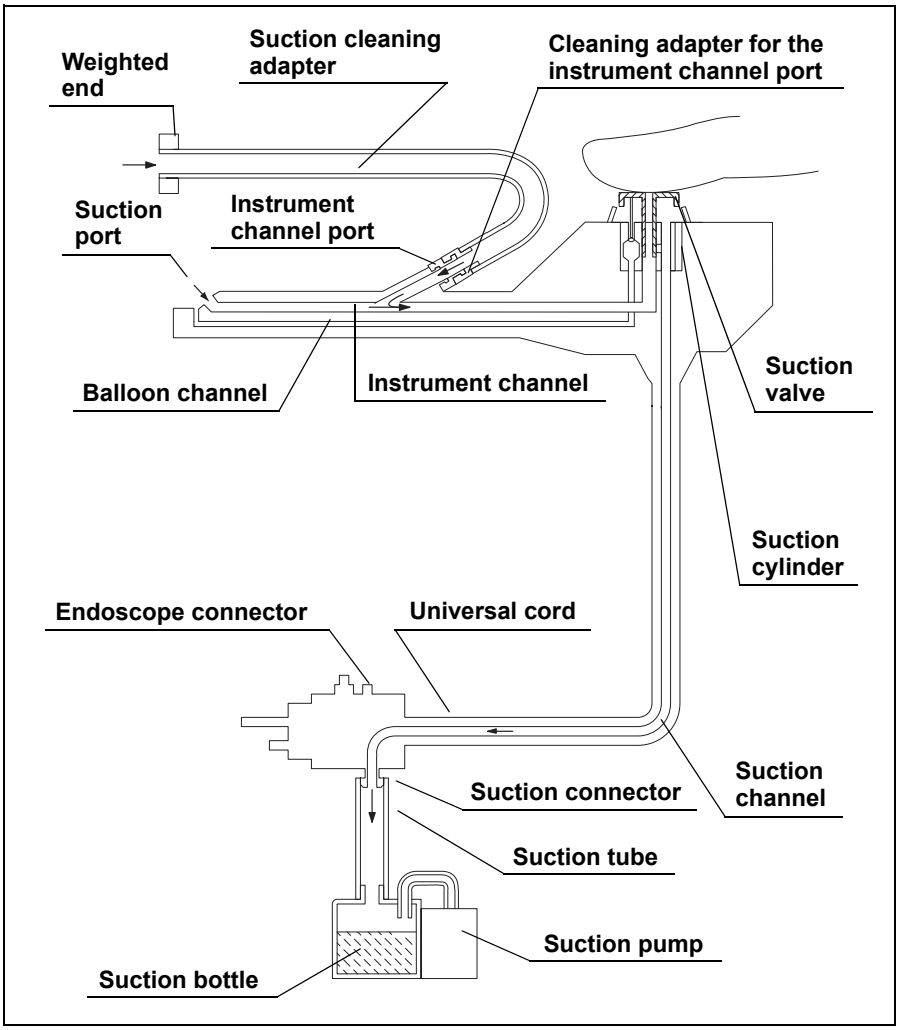


Figure 7.34

CAUTION

Alcohol is flammable. Handle with care.

Flushing detergent solution into the air/water and balloon channels

1. Attach the channel plug's biopsy valve cap to the cleaning adapter for instrument channel port (see Figure 7.35).
2. Lower the channel plug's cylinder plug onto the air/water and suction cylinders and slide the plug until it stops (see Figure 7.35).

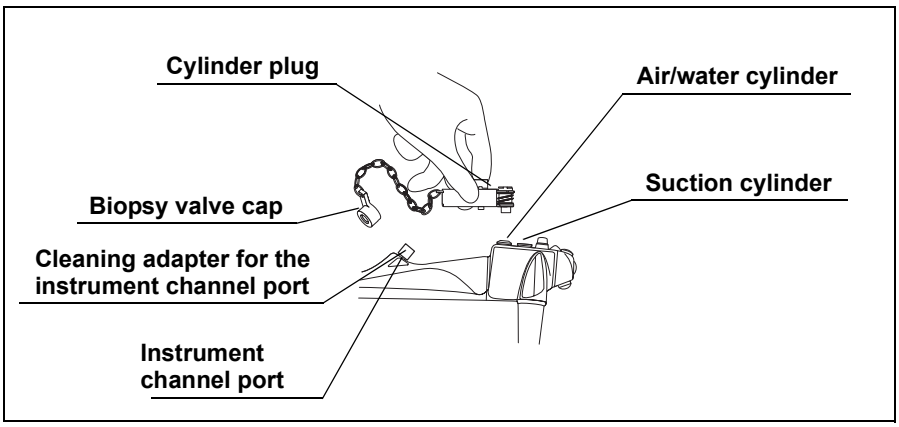


Figure 7.35

3. Attach the injection tube's connector plug to the air and water supply connectors on the endoscope connector (see Figures 7.36 and 7.37).
4. Attach the injection tube's air pipe port to the air pipe on the endoscope connector (see Figures 7.36 and 7.37).
5. Attach the injection tube's suction channel tube to the suction connector on the endoscope connector (see Figures 7.36 and 7.37).
6. Immerse the suction port of the injection tube in the detergent solution.

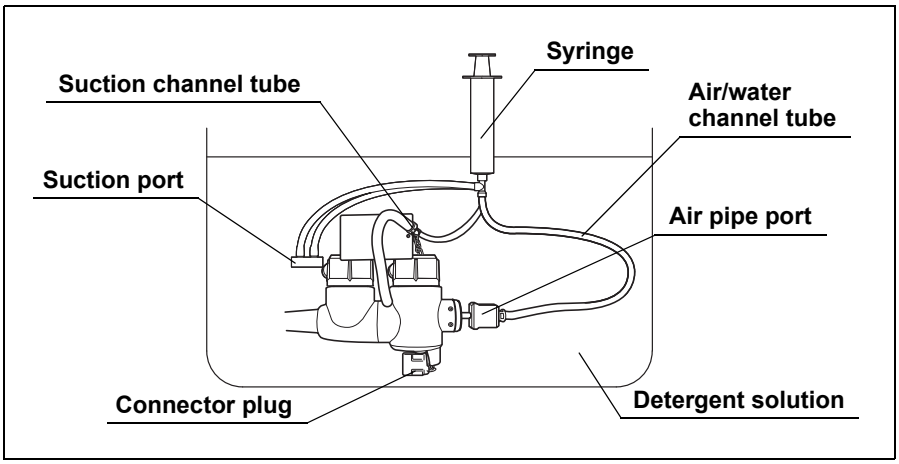


Figure 7.36

7. Attach the 30 cm^3 (30 ml) syringe to the injection tube's air/water channel port (see Figure 7.37).

8. Inject 150 cm^3 (150 ml) of detergent solution into the air/water channel and the balloon channel.

9. Detach the channel plug, the cleaning adapter for instrument channel port and injection tube from the endoscope, and leave all items immersed.

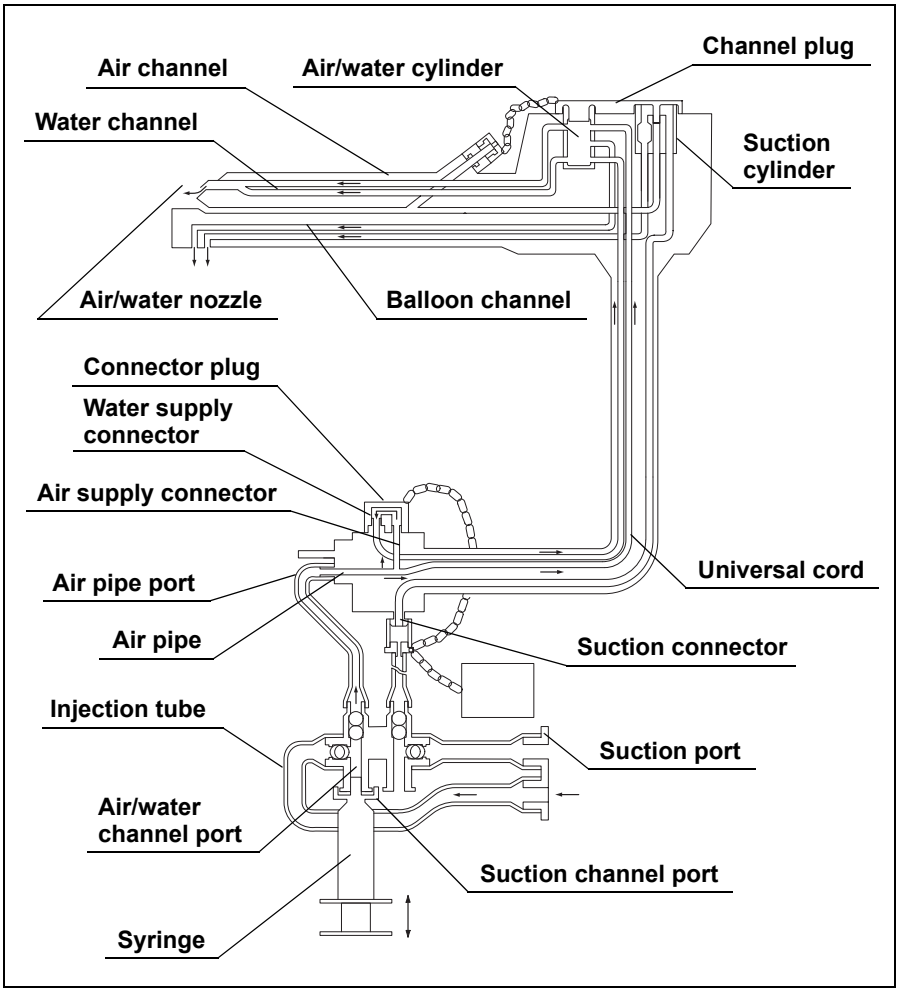


Figure 7.37

Flushing detergent solution into the elevator wire channel

1. Connect the washing tube to the elevator channel plug (see Figure 7.38).

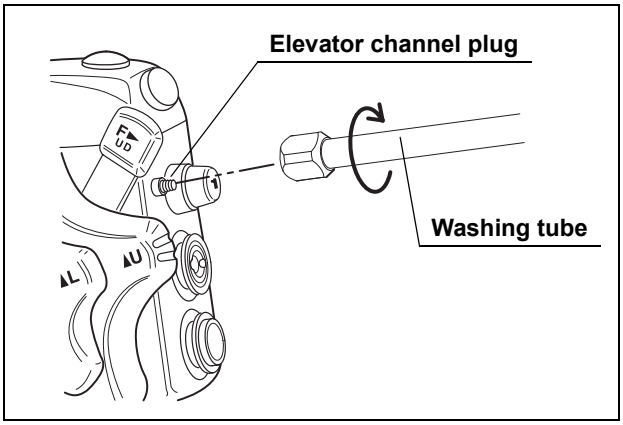


Figure 7.38

2. Use the 5 cm^3 (5 ml) syringe to inject 15 cm^3 (15 ml) of detergent solution into the elevator wire channel via the washing tube (see Figure 7.39).

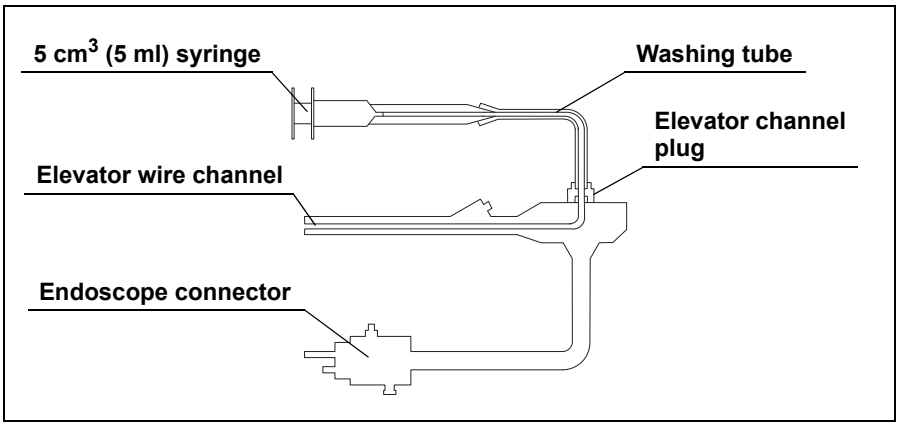


Figure 7.39

3. Disconnect the washing tube from the endoscope and immerse it in detergent solution.

Soaking the endoscope and all reprocessing equipment in detergent solution

1. Using a lint-free cloth, wipe all debris from the endoscope's external surfaces while the endoscope is immersed in the detergent solution.
2. Cover the basin with a tight-fitting lid to minimize the diffusion of detergent vapors.
3. Soak the endoscope and all reprocessing equipment for the amount of time and at the temperature and concentration recommended by the detergent manufacturer.
4. Remove the endoscope and all reprocessing equipment from the detergent solution.
5. Inspect all reprocessing equipment. If debris remains, ultrasonically clean at 33 – 48 kHz for 5 minutes.
6. Place the endoscope and all reprocessing equipment in clean water and gently agitate them to thoroughly rinse.

Removing detergent solution from all channels

1. Attach the channel plug, the cleaning adapter for instrument channel port and the injection tube to the endoscope. Place the suction port in clean water. Attach the channel plug's biopsy valve cap to the cleaning adapter for instrument channel port (see Figure 7.40).
2. Attach the 30 cm^3 (30 ml) syringe to the suction channel port and inject 150 cm^3 (150 ml) of clean water into the suction channel and the balloon channel (see Figures 7.37 and 7.40).
3. Attach the 30 cm^3 (30 ml) syringe to the injection tube's air/water channel port and inject 150 cm^3 (150 ml) of clean water into the air/water channel and the balloon channel (see Figures 7.37 and 7.40).
4. Connect the washing tube to the elevator channel plug (see Figure 7.38).
5. Attach the 5 cm^3 (5 ml) syringe to the washing tube and flush the elevator wire channel with 5 cm^3 (5 ml) of clean water (see Figure 7.39).
6. Remove the endoscope, together with all equipment, from the water.
7. Cover the distal end and control section of the endoscope with a clean, lint-free cloth.
8. Using the 30 cm^3 (30 ml) syringe, flush the air/water, balloon, and suction channels with 150 cm^3 (150 ml) of air, respectively, via the injection tube (see Figures 7.37 and 7.40).

9. Use the 5 cm^3 (5 ml) syringe, to flush the elevator wire channel with 10 cm^3 (10 ml) of air via the washing tube (see Figure 7.39).
10. Remove the clean, lint-free cloth from the distal end and the control section of the endoscope.
11. Detach the channel plug, the cleaning adapter for instrument channel port and injection tube from the endoscope.
12. Detach the washing tube from the endoscope.

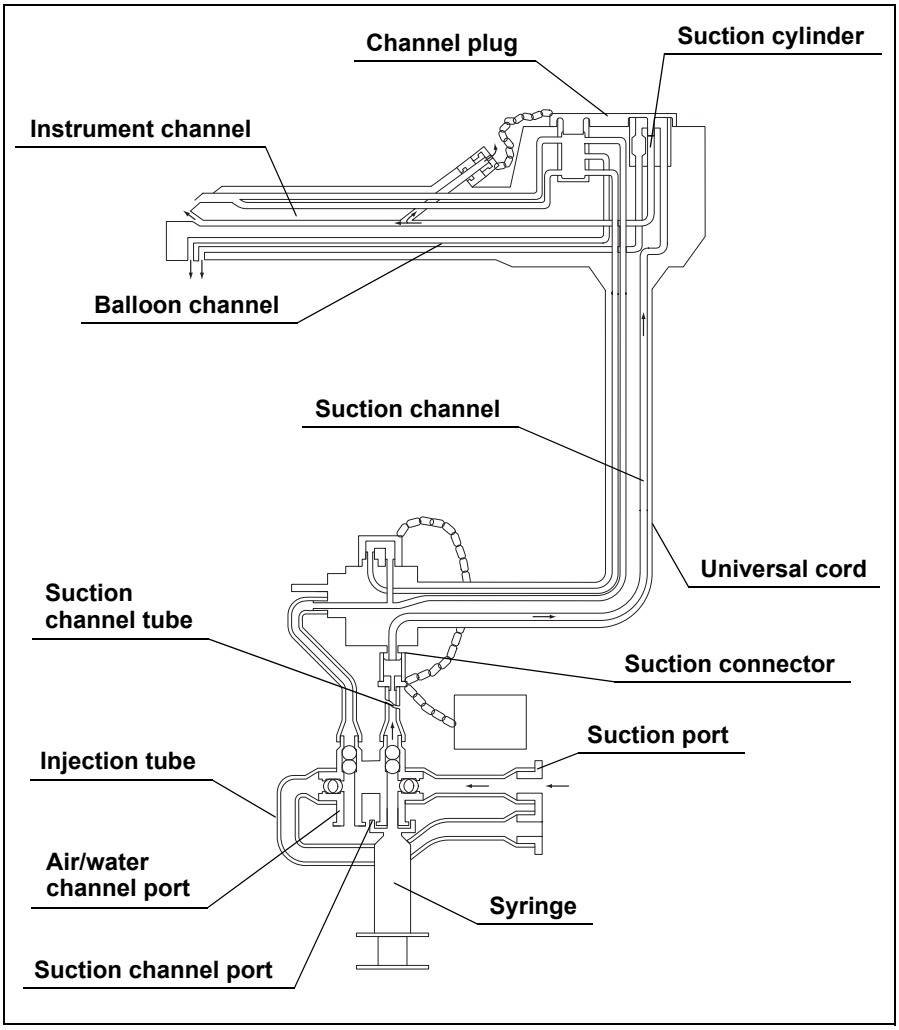


Figure 7.40

Dry external surfaces

1. Using a clean, lint-free cloth, wipe and dry the external surfaces of the endoscope and all equipment thoroughly.
2. Inspect the endoscope and all equipment for residual debris. Should debris remain, repeat the procedures given in this section.

Presoak for excessive bleeding and/or delayed reprocessing after each procedure

CAUTION

Follow the steps below only in case of excessive bleeding and/or delayed reprocessing; unnecessary immersions should be avoided. Consecutive extended immersions may damage the endoscope.

1. Fill a basin with detergent solution at the temperature and concentration recommended by the detergent manufacturer. Use a basin that is at least 40 cm by 40 cm (16” by 16”) in size and deep enough to allow the endoscope to be completely immersed.
2. Carefully coil the endoscope’s insertion tube and universal cord, and completely immerse the endoscope in the detergent solution.
3. Fill all channels with the detergent solution following the procedures described in this section.
4. Remove only reprocessing equipment from the detergent solution.
5. Cover the basin with a tight-fitting lid to minimize the diffusion of detergent vapors.
6. Soak the endoscope for 10 hours at the temperature and concentration recommended by the detergent manufacturer.
7. Remove the endoscope from the detergent solution.
8. After soaking the endoscope, manually clean it following the procedures described in this section.

7.6 High-level disinfection

WARNING

All disinfection steps should be performed with the endoscope and all equipment completely immersed in disinfectant solution. If the equipment is connected to the endoscope while they are immersed, or any part of the equipment is not immersed completely, disinfectant solution may not adequately contact all surfaces of the equipment.

After manual cleaning, disinfect the endoscope according to the procedures described below.

Equipment needed

Prepare the following equipment and wear appropriate personal protective equipment.

- Personal protective equipment
- Clean, lint-free cloths
- Large basin with a tight-fitting lid
- Disinfectant solution
- 30 cm^3 (30 ml) syringe
- 5 cm^3 (5 ml) syringe
- Channel plug (MAJ-621)
- Injection tube (MH-946)
- Washing tube (MH-974)
- Cleaning adapter for instrument channel port (MAJ-350)

Preparation

1. Fill a basin with disinfectant solution at the temperature and concentration recommended by the disinfectant manufacturer. Use a basin that is at least 40 cm by 40 cm (16” by 16”) in size and deep enough to completely immerse the endoscope.
2. Connect the cleaning adapter for the instrument channel port to the endoscope.
3. Attach the channel plug and the injection tube to the endoscope. Attach the channel plug’s biopsy valve cap to the cleaning adapter for instrument channel port (see Figures 7.35 and 7.36).
4. Connect the washing tube to the elevator channel plug (see Figure 7.38).

Flushing disinfectant solution into all channels

WARNING

Completely remove all air bubbles from all channels. Air bubbles may inhibit disinfection of the channel surface.

NOTE

Removal of air bubbles can be facilitated by forcefully injecting disinfectant solution into the channels.

1. Immerse the endoscope and all equipment in the disinfectant solution.
2. Confirm that the suction port of the injection tube is immersed in disinfectant solution.
3. Using the 30 cm^3 (30 ml) syringe, flush at least 150 cm^3 (150 ml) of disinfectant solution through the air/water and suction channels respectively. Confirm that no bubbles exit the distal end of the endoscope.
4. Using the washing tube and the 5 cm^3 (5 ml) syringe, flush 15 cm^3 (15 ml) of disinfectant solution through the elevator wire channel. Confirm that no bubbles exit the distal end of the endoscope.
5. While immersed in disinfectant solution, raise the forceps elevator and flush the vicinity of the forceps elevator with disinfectant solution using the 30 cm^3 (30 ml) syringe.
6. With the endoscope, channel plug, injection tube, cleaning adapter for the instrument channel port and washing tube completely immersed in disinfectant solution, disconnect all equipment from the endoscope. Leave the endoscope and all equipment immersed in the disinfectant solution.

Soaking the endoscope and all equipment in disinfectant solution

WARNING

All disinfection steps should be performed with the endoscope and all equipment completely immersed. If the equipment is disconnected while not immersed, disinfectant solution may not adequately contact all surfaces. As a result, the effectiveness of disinfection may be reduced.

1. With the endoscope and all equipment completely immersed in the disinfectant solution, disconnect all equipment from the endoscope. Leave the endoscope and all equipment immersed in the disinfectant solution.
2. Immerse the distal end in disinfectant solution, and move the elevator control lever in the “U” direction to slope the forceps elevator.
3. If air bubbles adhere to the surfaces of the endoscope and/or equipment, wipe them away using a clean, lint-free cloth.
4. Cover the basin with a tight-fitting lid to minimize the diffusion of disinfectant vapors.
5. Soak the endoscope and all equipment in disinfectant solution for the amount of time and at the temperature and concentration recommended by the disinfectant manufacturer.

Removing the endoscope and all equipment from disinfectant solution

1. Before removing the endoscope from the disinfectant solution, connect the channel plug, injection tube, cleaning adapter for the instrument channel port and washing tube to the endoscope. Attach the channel plug’s biopsy valve cap to the cleaning adapter for the instrument channel port.
2. Remove the injection tube’s suction port from the disinfectant solution.
3. Attach the 30 cm^3 (30 ml) syringe to the injection tube’s air/water channel port and flush the air/water channel with 150 cm^3 (150 ml) of air.
4. Attach the 30 cm^3 (30 ml) syringe to the injection tube’s suction channel port and flush the suction channel with 150 cm^3 (150 ml) of air.
5. Attach the 5 cm^3 (5 ml) syringe to the washing tube and flush the elevator wire channel with 15 cm^3 (15 ml) of air.
6. Remove the endoscope and all equipment from the disinfectant solution.
7. Disconnect all equipment from the endoscope.

7.7 Rinsing after high-level disinfection

WARNING

After reprocessing, purge the channels of the endoscope to thoroughly dry them. Otherwise, bacteria may proliferate in the channels and pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope.

After high-level disinfection, rinse the endoscope according to the procedures described below.
Use water of appropriate microbiological quality. Once removed from disinfectant solution, the instrument must be thoroughly rinsed with sterile water to remove any disinfectant residue. If sterile water is not available, fresh potable tap water or water that has been processed (e.g., filtered) to improve its microbiological quality may be used with 70% ethyl or isopropyl alcohol rinse (see “Nonsterile water rinse and alcohol flush” on page 137). Consult with your hospital’s infection control committee.

Equipment needed

Prepare the following equipment, and wear appropriate personal protective equipment.

- Personal protective equipment
- Sterile, lint-free cloths
- Sterile large basin with tight-fitting lid
- Sterile water for sterile water rinse
- Suction pump (with sterile suction tube)
- 30 cm^3 (30 ml) syringe
- 5 cm^3 (5 ml) syringe
- Channel plug (MAJ-621)
- Injection tube (MH-946)
- Washing tube (MH-974)
- Cleaning adapter for instrument channel port (MAJ-350)

If sterile water is not available, prepare the following equipment.

- Clean water for nonsterile water rinse
- Small basin with a tight-fitting lid
- Sterile cotton swabs
- 70% ethyl or isopropyl alcohol

CAUTION

Alcohol is flammable. Handle with care.

❍ Sterile water rinse

1. Fill a basin with sterile water. Use a basin that is at least 40 cm by 40 cm (16” by 16”) in size and deep enough to allow the endoscope to be completely immersed.
2. Immerse the endoscope, channel plug, injection tube and cleaning adapter for the instrument channel port in the sterile water. Using a sterile, lint-free cloth, thoroughly rinse and wipe all external surfaces.
3. Connect the cleaning adapter for the instrument channel port, the channel plug, and the injection tube to the endoscope. Place the suction port in sterile water.
4. Attach the 30 cm^3 (30 ml) syringe to the injection tube’s air/water channel port and inject 150 cm^3 (150 ml) of sterile water into the air/water channel and the balloon channel.
5. Attach the 30 cm^3 (30 ml) syringe to the suction channel port and inject 150 cm^3 (150 ml) of sterile water into the suction channel and the balloon channel.
6. Attach the washing tube to the elevator channel plug.
7. Using the 5 cm^3 (5 ml) syringe, inject 15 cm^3 (15 ml) of sterile water into the elevator wire channel.
8. Remove the endoscope, together with all equipment, from the water.
9. Using the 30 cm^3 (30 ml) syringe, flush the air/water and suction channels with 150 cm^3 (150 ml) of air.
10. Using the 5 cm^3 (5 ml) syringe, flush the elevator wire channel with 15 cm^3 (15 ml) of air.
11. Disconnect the injection tube only. Connect a sterile suction tube from the suction pump to the suction connector on the endoscope. Turn the suction pump ON and aspirate air for at least 15 seconds.

12. Turn the suction pump OFF and disconnect all equipment from the endoscope.
13. Use a sterile, lint-free cloth to thoroughly wipe and dry the external surfaces of the endoscope and all equipment.
14. Store the components following the instructions as described in Chapter 9, “Storage and Disposal”.

NOTE

Flushing the channels with 70% ethyl or isopropyl alcohol after rinsing them with sterile water facilitates drying inside the channels.

❍ Nonsterile water rinse and alcohol flush

1. Fill a small container with 70% ethyl or isopropyl alcohol.
2. Inject nonsterile water and air following the procedure given in “Sterile water rinse” on page 136.
3. Immerse the suction port of the injection tube in the alcohol. Using the 30 cm^3 (30 ml) syringe, flush the air/water and suction channels with 150 cm^3 (150 ml) of the alcohol, respectively.
4. Remove the suction port of the injection tube from the alcohol. Flush the air/water and suction channels with 150 cm^3 (150 ml) of air.
5. Using the 5 cm^3 (5 ml) syringe, flush the washing tube with 15 cm^3 (15 ml) of the alcohol through the elevator wire channel.
6. Using the 5 cm^3 (5 ml) syringe, flush the washing tube with 15 cm^3 (15 ml) of air through the elevator wire channel.
7. Disconnect all equipment from the endoscope.
8. Remove all equipment and the endoscope from the basin.
9. Use a sterile, lint-free cloth to thoroughly wipe and dry the external surfaces of the endoscope and all equipment.
10. Use a sterile, lint-free cloth moistened with alcohol to thoroughly wipe the external surfaces of the endoscope and all equipment.
11. Connect the cleaning adapter for instrument channel port, channel plug and injection tube to the endoscope. Using the 30 cm^3 (30 ml) syringe, flush the air/water channel with 150 cm^3 (150 ml) of air.
12. Using the washing tube and the 5 cm^3 (5 ml) syringe, flush 15 cm^3 (15 ml) of air through the elevator wire channel.

13. Disconnect the injection tube only. Connect a clean suction tube from the suction pump to the suction connector on the endoscope and aspirate air for 15 seconds.
14. Disconnect all equipment from the endoscope.
15. Use sterile cotton swabs to dry the inside of the air/water cylinder, suction cylinder, and instrument channel port.
16. Store the components following the instructions as described in Chapter 9, “Storage and Disposal”.

7.8 Sterilization

Ethylene oxide gas sterilization

As an alternative to high-level disinfection, the endoscope can be sterilized by ethylene oxide gas. After performing manual cleaning and drying as described in Section 7.3, “Precleaning” on page 103 and Section 7.5, “Manual cleaning” on page 113, follow the procedures given below.

CAUTION

- Exceeding the recommended parameters may cause equipment damage.
- If ethylene oxide gas sterilization is performed while the water-resistant caps are attached, the covering of the bending section can be damaged.

1. Dry the endoscope before ethylene oxide gas sterilization.
2. Remove the water-resistant caps before ethylene oxide gas sterilization (see Figure 7.41).
3. Seal the instrument in a package appropriate for ethylene oxide gas sterilization according to your hospital’s protocol.
4. Sterilize the package according to the recommended ethylene oxide gas exposure parameters as described in Section 6.5, “Ethylene oxide gas sterilization” on page 85 and the sterilizer manufacturer’s instructions.
5. Aerate the components following the minimum aeration parameters specified in Section 6.5, “Ethylene oxide gas sterilization” on page 85.
6. Store the components following the instructions given in Chapter 9, “Storage and Disposal”.

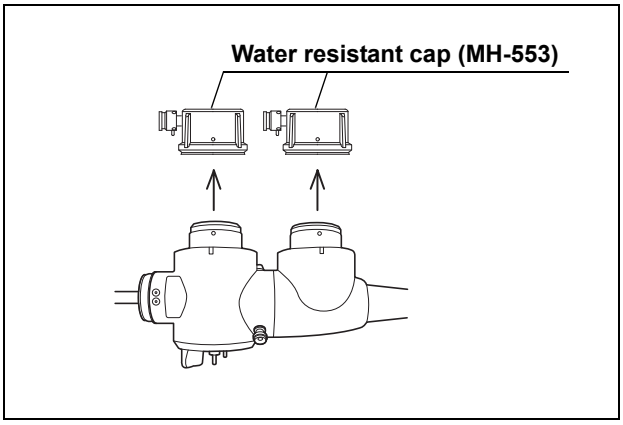


Figure 7.41

7.9 Cleaning, disinfection, and sterilization procedures for reusable parts and reprocessing equipment

WARNING

All reusable parts and reprocessing equipment must be cleaned and high-level disinfected or sterilized after each use. Otherwise, an infection control risk to the patient and/or operators can result.

This section includes cleaning, disinfection, and sterilization procedures for the reusable parts and reprocessing equipment listed below.

- Air/water valve (MAJ-1444)
- Suction valve (MAJ-1443)
- Air/water channel cleaning adapter (MAJ-629)
- Mouthpiece (MB-142)
- Biopsy valve (MAJ-853)
- Channel-opening cleaning brush (MH-507)
- Channel cleaning brush (BW-20T, BW-7L)
- Suction cleaning adapter (MH-856)
- Balloon applicator (MAJ-675)
- Cleaning brush (MAJ-1534)

Equipment needed

Prepare the following equipment, and wear appropriate personal protective equipment.

- Personal protective equipment
- Small basins with tight-fitting lids
- Clean water
- Detergent solution
- Channel cleaning brush or (BW-20T, BW-7L)
  single use channel cleaning brush (BW-201T)
- Soft brush
- Clean, lint-free cloths and/or sponges
- 30 cm^3 (30 ml) syringe
- Disinfectant solution
- Sterile water for sterile water rinse
- Sterile, lint-free cloths

If sterile water is not available, prepare the following equipment.

- Small basin with a tight-fitting lid
- 70% ethyl or isopropyl alcohol
- Single use combination cleaning brush (BW-412T)
- Single use single-ended cleaning brush (BW-400L)

Manual cleaning

CAUTION

- Make sure that the items immersed in detergent solution do not contact one another.
- Make sure not to scratch the seals on the air/water valve and air/water channel cleaning adapter with brushes, etc.

1. Fill a basin with clean water. Use a basin that is deep enough to completely immerse all equipment.
2. Fill a basin with the detergent solution at the temperature and concentration recommended by the detergent manufacturer. Use a basin that is deep enough to completely immerse all equipment.

3. Detach the biopsy valve's cap from the main body, before immersing in the detergent solution (see Figure 7.42).

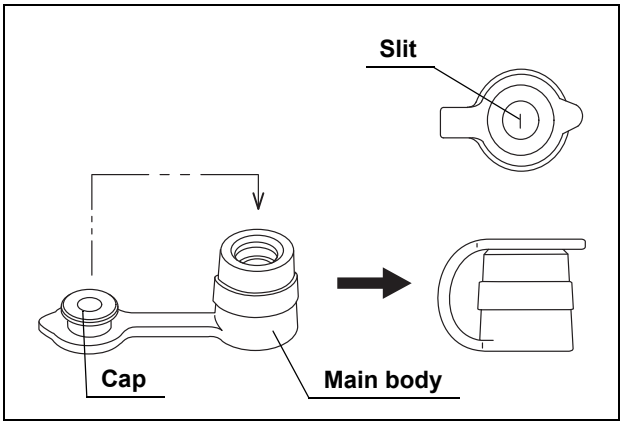


Figure 7.42

4. Immerse all equipment in the detergent solution. Using a clean, soft brush or lint-free cloth, meticulously clean all external surfaces in detergent solution.

5. Clean the bristles of the cleaning brushes (BW-20T, BW-7L and MH-507) or the single use single-ended cleaning brush (BW-400L) thoroughly while the brushes are immersed.

6. While immersed, depress and release the pistons of the air/water valve, suction valve and air/water channel cleaning adapter.

7. Using the channel cleaning brush (BW-20T, BW-7L), the single use channel cleaning brush (BW-201T), the single use combination cleaning brush (BW-412T), or the single use single-ended cleaning brush (BW-400L) thoroughly brush the hole of the suction valve and air/water valve, the openings of biopsy valve and balloon applicator until no debris can be seen (see Figures 7.43 and 7.44). Clean the bristles of the brush while it is immersed in detergent solution.

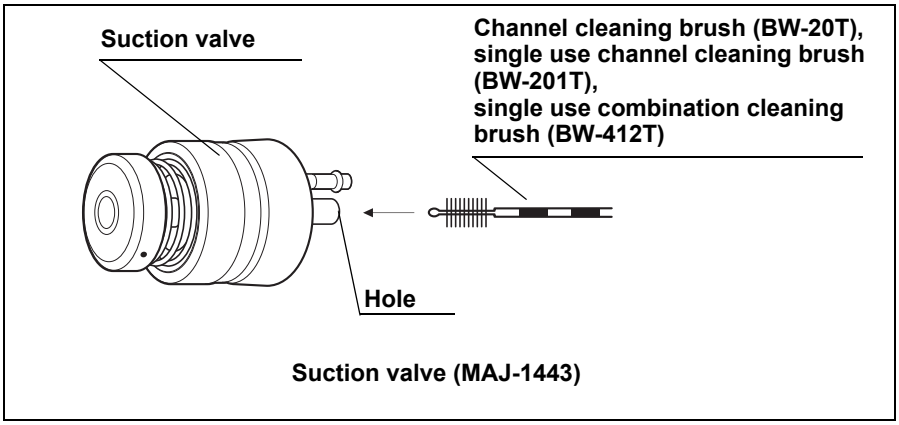


Figure 7.43

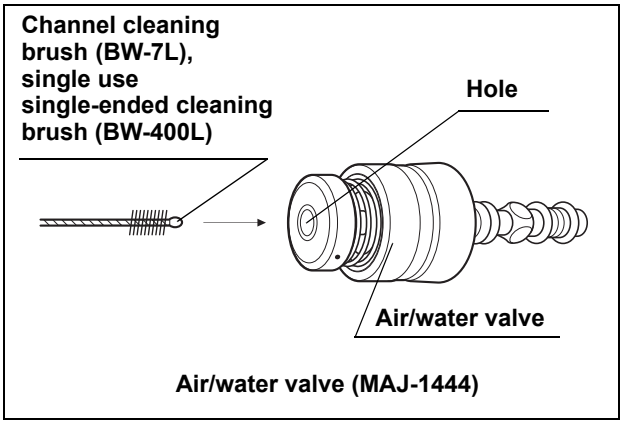

Channel cleaning brush (BW-7L), single use single-ended cleaning brush (BW-400L)
Hole
Air/water valve
Air/water valve (MAJ-1444)

Figure 7.44

8. To clean the suction cleaning adapter, attach the 30 cm^3 (30 ml) syringe and flush the tube thoroughly with detergent solution.
9. Soak all equipment for the amount of time and at the temperature recommended by the detergent manufacturer.
10. Remove all equipment from the detergent solution and place it in clean water.
11. Inspect all equipment. If debris remains, ultrasonically clean at 38 – 47 kHz for 5 minutes.
12. While immersed, depress and release the pistons of the air/water valve, suction valve and air/water channel cleaning adapter.
13. Attach the 30 cm^3 (30 ml) syringe to the suction cleaning adapter and flush the tube with the clean water.
14. Remove all equipment from the clean water.
15. Attach the 30 cm^3 (30 ml) syringe to the suction cleaning adapter and flush air to remove the clean water.
16. Use a clean, lint-free cloth to thoroughly wipe and dry the external surfaces of all equipment.

High-level disinfection

WARNING

- Completely remove all air bubbles from all equipment, including inner channels. Air bubbles remaining on the equipment prevent proper disinfection.
- All disinfection steps should be performed with all equipment completely immersed. If any part of the equipment is not immersed completely, disinfectant solution may not adequately contact all surfaces.

1. Fill a basin with disinfectant solution at the temperature and concentration recommended by the disinfectant manufacturer. Use a basin that is deep enough to completely immerse all equipment.
2. Immerse all equipment in the disinfectant solution.
3. Use a lint-free cloth and/or 30 cm^3 (30 ml) syringe, to wipe and/or flush all surfaces with the disinfectant solution to remove all air bubbles.
4. Use the 30 cm^3 (30 ml) syringe, to flush the interior and recessed parts of all equipment while immersed. Ensure that all air bubbles are expelled.
5. While immersed, depress and release the pistons of the valves and air/water channel cleaning adapter. Ensure that all air bubbles are expelled.
6. Use the 30 cm^3 (30 ml) syringe, to flush the recessed parts of the biopsy valve with disinfectant solution while the valve is immersed. Ensure that all air bubbles are expelled.
7. Rub the bristles of the channel cleaning brush and channel-opening cleaning brush to remove all air bubbles.
8. Use the 30 cm^3 (30 ml) syringe to flush the inside of the suction cleaning adapter thoroughly with disinfectant solution while immersed in the disinfectant solution. Ensure that all air bubbles are expelled.
9. Cover the basin with a tight-fitting lid to minimize the diffusion of disinfectant vapor. Soak all equipment in disinfectant solution for the amount of time and at the temperature and concentration recommended by the disinfectant manufacturer.
10. Remove the suction cleaning adapter from the disinfectant solution. Hold the adapter and tilt it to expel the disinfectant solution remaining in the adapter.
11. Remove all equipment from the disinfectant solution.

Rinsing after high-level disinfection

After high-level disinfection, rinse all equipment according to the procedures described below.
Use water of appropriate microbiological quality. Once removed from disinfectant solution, the instrument must be thoroughly rinsed with sterile water to remove any disinfectant residue. If sterile water is not available, fresh, potable tap water or water that has been processed (e.g., filtered) to improve its microbiological quality may be used in conjunction with 70% ethyl or isopropyl alcohol rinse (see “Nonsterile water rinse and alcohol flush” on page 137). Consult with your hospital’s infection control committee.

CAUTION

Alcohol is flammable. Handle with care.

❍ Sterile water rinse

1. Fill a small basin with sterile water. Use a basin that is deep enough to completely immerse all equipment.
2. Immerse all equipment in the sterile water.
3. Gently agitate the equipment to thoroughly rinse it.
4. Use the 30 cm^3 (30 ml) syringe to flush the interiors and recessed parts of all equipment with sterile water while immersed. Ensure that all air bubbles are expelled.
5. While immersed, depress and release the pistons of the air/water valve, suction valve, and air/water channel cleaning adapter. Ensure that all air bubbles are expelled.
6. Rub the bristles of the channel cleaning brush and channel-opening cleaning brush to remove all air bubbles.
7. Attach the 30 cm^3 (30 ml) syringe to the suction cleaning adapter and flush the adapter with 30 cm^3 (30 ml) of sterile water while immersed. Ensure that all air bubbles are expelled.
8. Remove the suction cleaning adapter from the sterile water. Hold the adapter and tilt it to expel the sterile water remaining in the adapter.
9. Use the 30 cm^3 (30 ml) syringe, to flush air to dry the inside of the suction cleaning adapter.
10. Remove all equipment from the sterile water.
11. Use a sterile, lint-free cloth to thoroughly wipe and dry all external surfaces.
12. Dry all equipment.

13. Store the components following the instructions given in Chapter 9, “Storage and Disposal”.

NOTE

Flushing the channels with 70% ethyl or isopropyl alcohol after rinsing them with sterile water facilitates drying inside the channels.

❍ Nonsterile water rinse and alcohol flush

1. Fill a small basin with clean water. Use a basin that is deep enough to completely immerse all equipment.
2. Immerse all equipment in clean water and perform Steps 3 through 11 as described in “Sterile water rinse” on page 144.
3. Fill a small basin with 70% ethyl or isopropyl alcohol.
4. Immerse all equipment in the alcohol.
5. Gently agitate the equipment in the alcohol.
6. Use the 30 cm^3 (30 ml) syringe, to flush the interiors and recessed parts of all equipment with alcohol to remove all air bubbles.
7. While immersed, depress and release the pistons of the air/water valve, suction valve, and air/water channel cleaning adapter. Ensure that all air bubbles are expelled.
8. Rub the bristles of the channel cleaning brush and channel-opening cleaning brush to remove all air bubbles.
9. Attach the 30 cm^3 (30 ml) syringe to the suction cleaning adapter and flush the adapter with 30 cm^3 (30 ml) of alcohol to remove all air bubbles.
10. Remove the suction cleaning adapter from the alcohol. Hold the adapter and tilt it to expel the alcohol remaining in the adapter.
11. Use the 30 cm^3 (30 ml) syringe to flush air to dry the inside of the suction cleaning adapter.
12. Remove all equipment from the alcohol.
13. Use a sterile, lint-free cloth, to thoroughly wipe and dry all external surfaces.
14. Dry all equipment thoroughly.
15. Store the components following the instructions as described in Chapter 9, “Storage and Disposal”.

Sterilization

CAUTION

Some components are compatible with several sterilization methods. However, certain components are not compatible with some methods, which can cause equipment damage.

In this section, the sterilization methods for the equipment compatible with ethylene oxide gas sterilization or steam sterilization (autoclaving) listed in Table 6.1 on page 82, are described below.

The channel plug (MAJ-621), the injection tube (MH-946), the cleaning adapter for instrument channel port (MAJ-350) and washing tube (MH-974) that have been cleaned and disinfected with the endoscope can also be sterilized by the procedures described below.

❍ Ethylene oxide gas sterilization

Follow the procedures described in Section 7.8, “Sterilization” on page 138.

❍ Steam sterilization (autoclaving)

After cleaning as described in “Manual cleaning” on page 140, steam sterilize (autoclave) the equipment according to the procedures described below.

WARNING

- Before taking the equipment package out of the autoclave, let it cool down to room temperature. Otherwise, it may cause burns.
- Effective sterilization will not be possible if items are packed tightly together in the autoclave; always pack items loosely.
- Inspect each equipment package for openings, tears, or other damage. If the equipment package is open or damaged, seal the equipment in a new package and resterilize it as described below.
- Allow the packages to dry within the autoclave, using the autoclave’s drying cycle (if available) or by opening the door of the autoclave and allowing the packages to air-dry. Handling a wet package can compromise its sterility.

CAUTION

Sudden changes in temperature may damage the instruments.

1. Seal the individual parts or equipment separately in packages appropriate for steam sterilization (autoclaving) according to your hospital's protocol.
2. Steam sterilize the packages according to the recommended steam sterilization (autoclaving) exposure parameters as described in Section 6.6, "Steam sterilization (autoclaving) of accessories" on page 87 and the sterilizer manufacturer's instructions.
3. Following steam sterilization (autoclaving), let all components gradually cool down to room temperature.
4. Store the components following the instructions as described in Chapter 9, "Storage and Disposal".

7.10 Care of the ultrasonic cable (MAJ-1597)

Equipment needed

- Clean, lint-free cloth
- Neutral detergent
- 70% ethyl or isopropyl alcohol

Care

1. If the cable is soiled with blood or other potentially infectious materials, wipe off all gross debris using a soft, lint-free cloth moistened with neutral detergent.
2. To remove dust, dirt and other non-patient debris, wipe the cable's surface with a soft, lint-free cloth moistened with 70% ethyl or isopropyl alcohol.
3. Make sure that the cable is completely dry.

WARNING

Alcohol is not a sterilant or high-level disinfectant.

CAUTION

- Never apply water to the ultrasonic cable. Equipment damage can result.
- The ultrasonic cable is not waterproof. Never immerse it in disinfectant solution or any other fluids.

Chapter 8 Cleaning and Disinfection Equipment

The endoscope is compatible with some endoscope reprocessors recommended by Olympus. Refer to the instruction manual for the endoscope reprocessor for details on operation.

WARNING

- Thoroughly clean the endoscope as described in Chapter 7, “Cleaning, Disinfection, and Sterilization Procedures” before reprocessing the endoscope in an endoscope reprocessor. If an endoscope that has not been thoroughly manually cleaned is placed into the endoscope reprocessor, debris attached to the endoscope may impair the cleaning and disinfection capabilities of the reprocessor, and the endoscope can pose an infection control risk to the patient and/or operators who perform the next procedure with it. Note that if the instrument is not precleaned immediately after the procedure, patient debris may solidify, which could impair proper cleaning and disinfection of the endoscope. Refer to the endoscope reprocessor’s instruction manual for details on proper connection of the endoscope to the reprocessor and operation of the reprocessor.
- Olympus only confirms validation of endoscope reprocessors it recommends. When using an endoscope reprocessor that is not recommended by Olympus, the endoscope reprocessor’s manufacturer is responsible for validation of the reprocessor with the endoscope models listed in this instruction manual.
- Before using an endoscope reprocessor, confirm that it is capable of reprocessing the endoscope including all channels. If you are uncertain as to the ability of your endoscope reprocessor to clean and high-level disinfect the endoscope including all channels, contact the endoscope reprocessor’s manufacturer for specific instructions and/or information on connectors. Insufficient cleaning and disinfection or sterilization of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope.

- When cleaning and disinfecting an endoscope in an endoscope reprocessor, use connectors that are specifically compatible with the endoscope model. Otherwise, insufficient cleaning and disinfection or sterilization of the endoscope may occur, which could pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope. The applicable connectors for each endoscope model should be listed in the instruction manual for the endoscope reprocessor. If your endoscope model is not listed in that instruction manual, please contact the manufacturer of the endoscope reprocessor.
- Some endoscope reprocessor are not designed to reprocess an elevator wire channel. If the elevator wire channel cannot be reprocessed by the endoscope reprocessor, clean, disinfect, and sterilize the endoscope according to procedures described in Chapter 7, “Cleaning, Disinfection, and Sterilization Procedures”.
- If using the endoscope reprocessor (EW-30, OER, OER-Pro, OER-AW), the GF-UCT180 can not be reprocessed with any other endoscopes. Only one unit of the GF-UCT180 can be reprocessed. GF-UCT180 can be reprocessed only one by one. Otherwise, insufficient cleaning and/or disinfection of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope.
- If using the endoscope reprocessor recommended by Olympus, be sure to attach the appropriate cleaning/connecting tube and retaining rack (see Table 8.1). Otherwise, insufficient cleaning and disinfection of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope. The applicable connectors for the endoscope model should be listed in the instruction manual for the endoscope reprocessor or in Table 8.1. If the endoscope and endoscope reprocessor is not listed in the instruction manual or in Table 8.1, please contact Olympus.

	Cleaning/connecting tube	Retaining rack
OER *1 **EW-30** *1	MAJ-33, MAJ-41, MAJ-43	–
OER-A *1	MAJ-825, MAJ-838	MAJ-840
OER-AW*1	MAJ-1501, MAJ-1517	MAJ-840
OER-Pro*1	MAJ-1501, MAJ-1517	MAJ-840

Table 8.1

∗1 These products may not be available in some areas.

	OER-Pro	OER-AW
GF-UCT180	Group3*1	Group3*1

Table 8.2

∗1 Group shows the endoscopes that can be reprocessed with this endoscope, and it is defined by the “List of Conpatible Endoscopes/Connecting Tubes” of OER-Pro and OER-AW. Refer to the “List of Compatible Endoscopes/Connecting Tubes” for endoscopes that can be reprocessed with this endoscope before using OER-Pro and OER-AW.

Be sure to attach all required connectors to the endoscope and accessories. For details concerning appropriate connectors, refer to the instructions of the AER manufacturer.
Manually clean and disinfect or sterilize any endoscopes and accessories which are not compatible withe the AER.

Chapter 9 Storage and Disposal

WARNING

- After reprocessing, keep the endoscope and accessories separate from any contaminated equipment. If the clean endoscope and accessories become contaminated between procedures, they could present an infection control risk to the patient and/or operators in the subsequent procedure.
- To prevent contamination of the reprocessed endoscope and accessories, be sure to keep the storage cabinet clean.
- The storage cabinet must be clean, dry, well ventilated and maintained at ambient temperature. Storing the endoscope in direct sunlight, at high temperatures, in high humidity or exposed to ozone, X-rays and/or ultraviolet-rays may damage the endoscope and/or present an infection control risk.
- Prior to storage, detach all removable parts from the endoscope. It will allow air to circulate through the internal lumens of the endoscope and will assist drying.
- Do not store the endoscope in the carrying case. Use the carrying case only for shipping the endoscope. Routinely storing the endoscope in a humid, nonventilated environment, such as the carrying case, may present an infection control risk.
- The package containing the balloons also contains a deoxidizer to maintain a deoxygenated condition until the package is opened. After the package is opened, the balloons will gradually deteriorate. To minimize deterioration, always keep the package sealed.

9.1 Storage of the endoscope

CAUTION

When storing the endoscope, make sure that the forceps elevator is not raised or it is not strike any objects. This could damage forceps elevator.

1. Detach all equipment (the air/water valve, suction valve, biopsy valve, and water-resistant cap) from the endoscope.
2. Confirm that all surfaces of the endoscope (especially the interior of the channels, the distal end, lens, and electrical contacts) are completely dry.
3. Place the endoscope's angulation locks in the "F▶" position.
4. Hang the endoscope in the storage cabinet with the distal end hanging freely. Make sure that the insertion section hangs vertically and as straight as possible.

9.2 Storage of the balloon

WARNING

Do not store the sterile package containing the instrument in place where it will be damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised and pose an infection control risk.

Store the balloon at room temperature, in a clean and dry environment. Do not store it in direct sunlight. If you have any questions about any information in this manual, contact Olympus.

9.3 Storage of reusable parts and reprocessing equipment

1. Confirm that all reusable parts and reprocessing equipment are dry.
2. Store all reusable pars loosely in a storage cabinet.
3. Store all reprocessing equipment in a container, then place the container in the storage cabinet.

9.4 Storage of the ultrasonic cable

CAUTION

The storage cabinet must be clean, dry, well ventilated, and maintained at ambient temperature. Storing the ultrasonic cable in direct sunlight, at high temperatures, in high humidity, or exposed to X-rays and/or ultraviolet-rays may damage the ultrasonic cable.

1. Make sure the ultrasonic cable is completely dry before storage.
2. The ultrasonic cable should be stored without being tightly coiled or twisted.

9.5 Disposal

When disposing of this endoscope or any of its components, follow all applicable national and local laws and guidelines.

Chapter 10 Troubleshooting

If the endoscope is visibly damaged, does not function as expected, or is found to have irregularities during the inspection described in Chapter 3, “Preparation and Inspection”, do not use the endoscope. Contact Olympus.
Some problems that appear to be malfunctions may be correctable by referring to Section 10.1, “Troubleshooting guide” on page 154. If the problem cannot be resolved by the described remedial action, stop using the endoscope and send it to Olympus for repair.
Olympus does not repair accessory parts. If an accessory part becomes damaged, contact Olympus to purchase a replacement.

WARNING

- Never use the endoscope on a patient if any irregularity is observed. Damage or irregularity in the instrument may compromise patient or user safety and may result in more severe equipment damage.
- If any parts of the endoscope fall off inside the patient body due to equipment damage or failure, stop using the endoscope immediately and retrieve the parts in an appropriate way.

Should any irregularity in the function of the endoscope and/or endoscopic image be observed during use, stop the examination immediately and carefully withdraw the endoscope from the patient as described in Section 10.2, “Withdrawal of the endoscope with an irregularity” on page 159.

10.1 Troubleshooting guide

The following table shows the possible causes of and countermeasures against troubles that may occur due to equipment setting errors or deterioration of consumables.
Troubles or failures due to other causes than those listed below should be serviced. As repair performed by persons who are not qualified by Olympus could cause patient or user injury and/or equipment damage, be sure to contact Olympus for repair following the instructions given in Section 10.3, “Returning the endoscope for repair” on page 161.

Endoscope functions

❍ Angulation

Irregularity description	Possible cause	Solution
Resistance is encountered when rotating angulation control knob(s).	The angulation lock(s) is engaged.	Rotate angulation lock(s) in the "F▶" direction.

❍ Air/water feeding

Irregularity description	Possible cause	Solution
No air feeding.	The air pump is not operating.	Press the "LOW", "MED", "HIGH" button on the light source as described in the light source's instruction manual.
	The air/water valve is damaged.	Replace it with a new one.
No water feeding.	The air pump is not operating.	Press the "LOW", "MED", "HIGH" button on the light source as described in the light source's instruction manual.
	There is no sterile water in the water container.	Add sterile water to fill the container to the specified water level.
	The air/water valve is damaged.	Replace it with a new one.
The air/water valve is sticky.	The air/water valve is dirty.	Remove the air/water valve. Reprocess the air/water valve and then attach it again.
	The air/water valve is damaged.	Replace it with a new one.
The air/water valve cannot be attached.	An incorrect air/water valve is used.	Use a correct air/water valve.
	The air/water valve is damaged.	Replace it with a new one.

❍ Suction

Irregularity description	Possible cause	Solution
The suction is absent or insufficient.	The biopsy valve is not attached properly.	Attach it correctly.
	The biopsy valve is damaged.	Replace it with a new one.
	The suction pump is not set properly.	Adjust the suction pump's setting as described in its instruction manual.
	The suction valve is damaged.	Replace it with a new one.
The suction valve is sticky.	The suction valve is dirty.	Remove the suction valve. Reprocess the suction valve and attach it again.
	The suction valve is damaged.	Replace it with a new one.
The suction valve cannot be attached.	The suction valve is damaged.	Replace it with a new one.
	An incorrect suction valve is used.	Use a correct suction valve.
Liquid leaks out of the biopsy valve.	The biopsy valve is damaged.	Replace it with a new one.
	The biopsy valve is not attached properly.	Attach it correctly.

❍ Image quality or brightness

Irregularity description	Possible cause	Solution
An image is abnormal.	An incompatible video system center is being used.	Use a compatible video system center.
	An incompatible light source is being used.	Use a compatible light source.
There is no video image.	Not all power switches are ON.	Turn all power switches ON.
An image is not clear.	The objective lens is dirty.	Feed water to remove mucus, etc.
An image is excessively dark or bright.	The light source is not set properly.	Adjust the light source's setting as described in its instruction manual.

❍ EndoTherapy accessories

Irregularity description	Possible cause	Solution
An EndoTherapy accessory does not pass through the instrument channel smoothly.	An incompatible EndoTherapy accessory is being used.	Refer to the “System chart” in the Appendix and select a compatible EndoTherapy accessory. Confirm that the color code on the EndoTherapy accessory matches that on the endoscope. Although the color code of the GF-UCT180 is orange, do not use EndoTherapy accessories designed for a Ø 4.2 mm or Ø 6.0 mm channel, use only EndoTherapy accessories designed for a o 3.7 mm channel.
The elevator control lever does not operate smoothly.	The elevator wire or the elevator wire channel is dirty.	Clean and disinfect or sterilize the elevator wire channel as described in Chapter 7, “Cleaning, Disinfection, and Sterilization Procedures” that has the model number of your endoscope on the cover.

❍ Others

Irregularity description	Possible cause	Solution
The remote switch does not work.	The wrong remote switch is operated.	Operate the correct remote switch.
	The remote switch function has been set incorrectly.	Set the remote switch function correctly as described in the video system center’s instruction manual.

❍ Ultrasound function (display monitor image)

Irregularity description	Possible cause	Solution
Echo appears where there is no object.	Multiple echoes generated from an object with strong reflection.	Move the endoscope's distal end to another position and check to see if the echo in question moves to a greater degree than other echoes. If this happens, multiple echoes have coalesced and disturbed the ultrasound image. Keep the endoscope's distal end away from any object with strong reflection.

❍ Balloon water feeding

Irregularity description	Possible cause	Solution
No water is fed into the balloon and/or no aspiration.	The air/water and/or suction valve is dirty.	Reprocess the valve.
	The balloon water channel is dirty.	Reprocess the channel.
	There is not enough water in water container when inflating/aspirating the balloon.	• Fill the container with enough sterile deaerated water. • Cover the hole of the air/water valve and depress the valve to the first stage for about 15 seconds. After this procedure, completely depress the valve until the balloon inflates (It generally takes about 30 seconds).
	The balloon channel is obstructed.	Reprocess the channel.
	The balloon supply port is obstructed by the sterile cotton thread.	Remove the thread from the balloon water supply port. Tie the cotton thread at the balloon attachment groove.

10.2 Withdrawal of the endoscope with an irregularity

If an irregularity occurs while the endoscope is in use, take proper measures as described in either “Withdrawal when the WLI and NBI endoscopic images appear on the monitor”, “Withdrawal when EITHER the WLI or the NBI endoscopic image does not appear on the monitor”, “Withdrawal when all endoscopic images do not appear on the monitor or a frozen image cannot be restored” below. After withdrawal, return the endoscope for repair as described in Section 10.3, “Returning the endoscope for repair” on page 161.

WARNING

If the endoscope or EndoTherapy accessory cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Should any irregularity be observed, immediately contact Olympus. Forcibly withdrawing the endoscope or EndoTherapy accessory may cause patient injury, bleeding, and/or perforation.

Withdrawal when the WLI and NBI endoscopic images appear on the monitor

1. Turn all equipment OFF except the video system center, light source, monitor, and suction pump.
2. When the NBI endoscopic image is displayed, switch to the WLI endoscopic image by operating the video system center and light source.
3. When using an EndoTherapy accessory, close the tip of the EndoTherapy accessory and/or retract it into its sheath. Then withdraw the EndoTherapy accessory slowly while lowering the forceps elevator gradually.
4. Aspirate accumulated air, blood, mucus, or other debris by depressing the suction valve to the first stage.
5. Turn the UP/DOWN and RIGHT/LEFT angulation locks in the “F▶” direction to release them.
6. Carefully withdraw the endoscope while observing the endoscopic image. Remove the mouthpiece from the patient’s mouth.

Withdrawal when EITHER the WLI or the NBI endoscopic image does not appear on the monitor

1. Turn all equipment OFF except the video system center, light source, monitor, and suction pump.
2. Operate the video system center and the light source to switch to the endoscopic image that is still displayed.
3. Follow the procedure of Step 3 above in “Withdrawal when the WLI and NBI endoscopic images appear on the monitor”. Carefully withdraw the endoscope under the visible observation mode when the WLI endoscopic image is not displayed.

Withdrawal when all endoscopic images do not appear on the monitor or a frozen image cannot be restored

1. Turn all equipment OFF except the video system center, light source, monitor, and suction pump.
2. Turn the video system center and light source OFF and then ON again. If the WLI or NBI endoscopic image appears or the frozen image is restored, follow the procedure given in “Withdrawal when EITHER the WLI or the NBI endoscopic image does not appear on the monitor”, beginning from Step 2. If all endoscopic images still do not appear or the frozen image cannot be restored, perform the following steps.
3. Turn the video system center, light source, monitor, suction pump OFF.
4. When using an EndoTherapy accessory, withdraw the EndoTherapy accessory slowly while the tip of the EndoTherapy accessory is closed and/or retracted into its sheath while lowering the forceps elevator gradually.
5. Turn the UP/DOWN and RIGHT/LEFT angulation locks in the “F▶” direction to release them.
6. Turn the UP/DOWN and RIGHT/LEFT angulation control knobs to their respective neutral positions (see Figure 3.4 on page 32).
7. Release the angulation control knobs and carefully withdraw the endoscope. Remove the mouthpiece from the patient’s mouth.

10.3 Returning the endoscope for repair

WARNING

Thoroughly clean and high-level disinfect or sterilize the endoscope before returning it for repair. Improperly reprocessed equipment poses an infection control risk to each person who handles the endoscope within the hospital or at Olympus.

CAUTION

Olympus is not liable for any injury or damage that occurs as a result of repairs attempted by non-Olympus personnel.

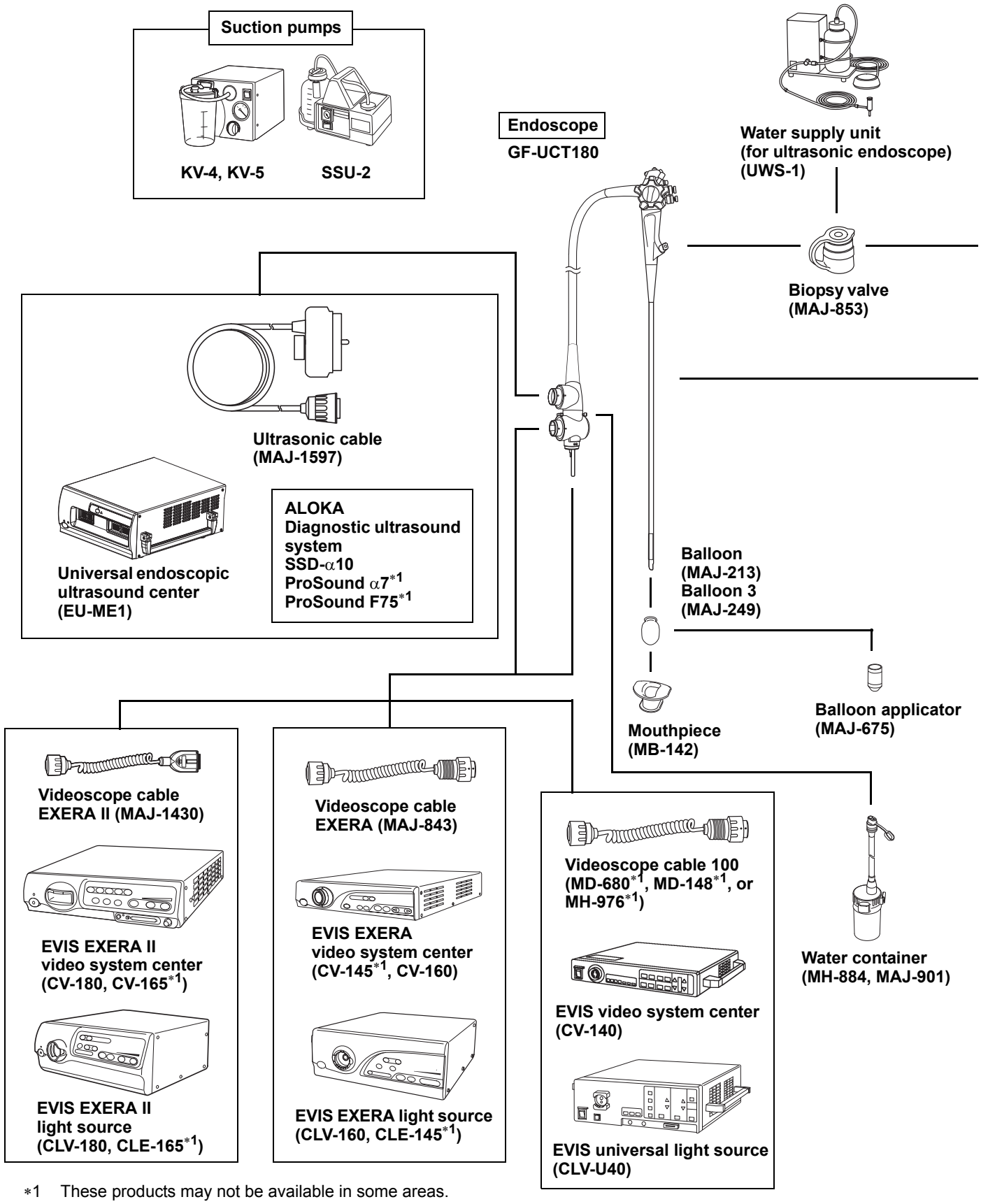
Before returning the endoscope for repair, contact Olympus. With the endoscope, include a description of the malfunction or damage and the name and telephone number of the individual at your location who is most familiar with the problem. Also include a repair purchase order.
When returning the endoscope for repair, follow the instructions given in “Transporting outside the hospital” on page 75.

Appendix A: System Chart

The recommended combinations of equipment and accessories that can be used with this instrument are listed below. Some items may not be available in some areas. New products released after the introduction of this instrument may also be compatible for use in combination with this instrument. For further details, contact Olympus.

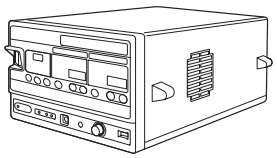
WARNING

If combinations of equipment other than those shown below are used, the full responsibility is assumed by the medical treatment facility.

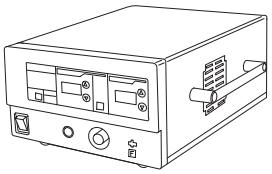


*1 These products may not be available in some areas.

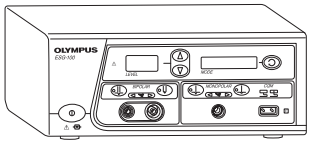
Electrosurgical units



UES-20, UES-30



PSD-30, PSD-60



ESG-100

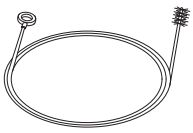
EndoTherapy accessories

See next page.

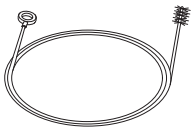
Electrosurgical accessories

See next page.

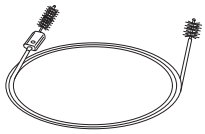
Cleaning and disinfection equipment



Channel cleaning brush (BW-7L*1) or single use single-ended cleaning brush (BW-400L*1)



Channel cleaning brush (BW-20T) or single use channel cleaning brush (BW-201T*1)

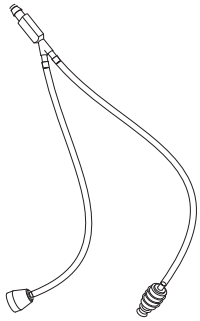


Single use combination cleaning brush (BW-412T*1)

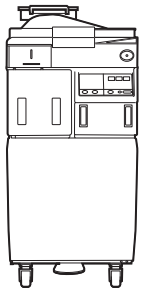
Channel-opening cleaning brush (MH-507) or single use channel-opening cleaning brush (MAJ-1339*1)

Cleaning brush (MAJ-1534)

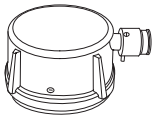
Leakage tester (MB-155)



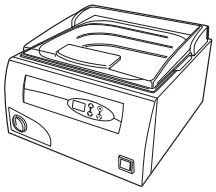
Suction cleaning adapter (MAJ-222)



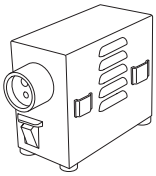
Endoscope washer (EW-30*1), Endoscope reprocessor (OER*1, OER-A*1, OER-AW*1, OER-Pro*1)



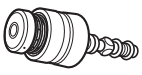
Water-resistant cap (MH-553)



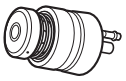
Ultrasonic cleaner (KS-2, ENDOSONIC)



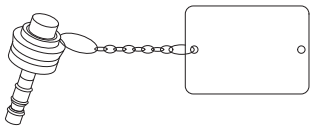
Maintenance unit (MU-1)



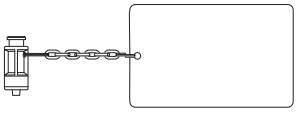
Air/water valve (MAJ-1444)



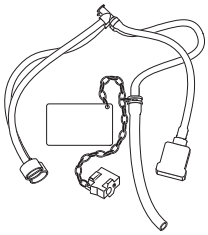
Suction valve (MAJ-1443)



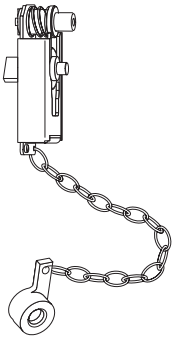
Air/water channel cleaning adapter (MAJ-629)



Cleaning adapter for instrument channel port (MAJ-350)

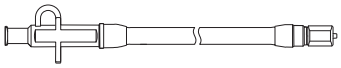


Injection tube (MH-946)



Channel plug (MAJ-621)

Suction cleaning adapter (MH-856)

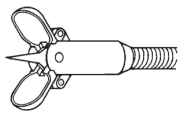
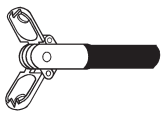


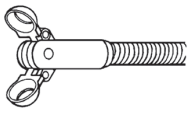
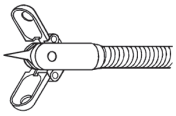
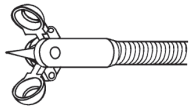
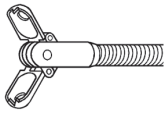
Washing tube (MH-974)

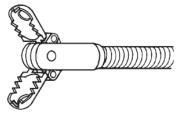
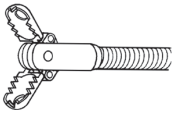
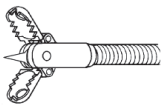
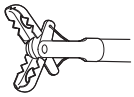
*1 These products may not be available in some areas.

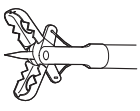
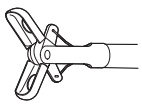
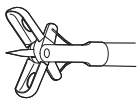
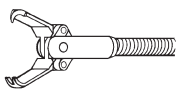
❍ EndoTherapy accessories

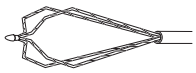
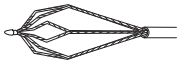
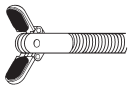
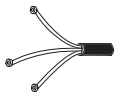
Please not that some of the accessories may not be available in some areas.

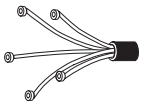
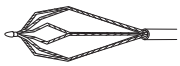
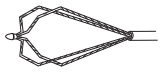
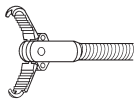
	Biopsy forceps			
	With needle	**Rat tooth**	**Alligator type**	**Alligator type with rat tooth**
Endoscope				
GF-UCT180	**FB-13Q-1**	**FB-39Q-1, FB-40Q-1**	**FB-45Q-1**	**FB-46Q-1**

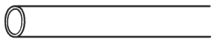
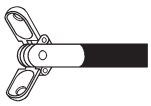
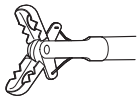
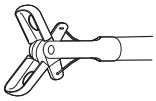
	Biopsy forceps (fenestrated)			
	Standard	**Elongated cups with needle**	**With needle**	**Rat tooth**
Endoscope				
GF-UCT180	**FB-19N-1, FB-26N-1, FB-28R-1**	**FB-24Q-1**	**FB-50Q-1**	**FB-37U-1**

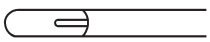
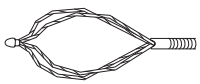
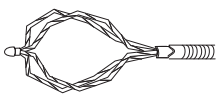
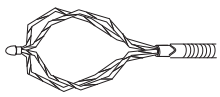
	Biopsy forceps (fenestrated)			Disposable biopsy forceps
	Alligator jaws and rat tooth (swinging type)	**Alligator jaws and rat tooth (swinging type/elongated cups)**	**Alligator jaws and rat tooth with needle (swinging type/ elongated cups)**	**Alligator jaws-step**
Endoscope				
GF-UCT180	**FB-53Q-1**	**FB-54Q-1**	**FB-55Q-1**	**FB-212U**

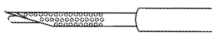
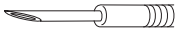
	Disposable biopsy forceps			Grasping forceps
	Alligator jaws-step with needle	**Oval**	**Oval with needle**	**Rat tooth**
Endoscope				
GF-UCT180	**FB-222U**	**FB-232U**	**FB-242U**	**FG-14P-1**

	Grasping forceps			
	Basket type	**Flower basket type**	**Rubber tips (non-latex)**	**Tripod type**
Endoscope				
GF-UCT180	**FG-16U, FG-18Q-1, FG-22Q-1, FG-23Q-1**	**FG-301Q**	**FG-20P-1**	**FG-45U-1**

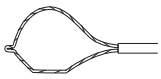
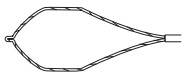
	Grasping forceps	**Disposable grasping forceps**		**Rotatable grasping forceps**
	Pentapod type	**Flower basket type**	**Basket type**	**Rat tooth with alligator type**
Endoscope				
GF-UCT180	**FG-46U-1**	**FG-401Q**	**FG-402Q, FG-403Q**	**FG-44NR-1**

	Washing pipe	**Hot biopsy forceps**	**Disposable hot biopsy forceps**	
	Standard type		**Alligator jaws-step**	**Oval**
Endoscope				
GF-UCT180	**PW-1V-1**	**FD-5U**	**FD-210U**	**FD-230U**

	Heat probe	**Mechanical lithotriptor**		**Disposable mechanical lithotriptor**
		Basket type	**Slide type**	**Slide type**
Endoscope				
GF-UCT180	**CD-21Z, CD-120U**	**BML-2Q-1**	**BML-4Q-1**	**BML-202Q, BML-203Q, BML-204Q**

Endoscope	Measuring device	Aspiration needle	
	Straight type	Disposable	Reuseable
			
GF-UCT180	M1-2U	NA-200H-8022	NA-11J-KB

❍ Electrosurgical accessories

Endoscope	Electrosurgical snare			
	Crescent	Hexagonal	Oval	Mini oval
				
GF-UCT180	SD-5U-1, SD-7P-1	SD-6U-1, SD-8P-1	SD-9U-1, SD-11U-1	SD-12U-1, SD-13U-1

Endoscope	Electrosurgical snare		Disposable electrosurgical snare	
	Oval (with thorns)	Mini Oval (with thorns)	Ex-mini oval	Mini oval
GF-UCT180	SD-16U-1	SD-17U-1	SD-210U-10, SD-240U-10	SD-210U-15, SD-240U-15

Endoscope	Disposable electrosurgical snare		
	Oval	Crescent	Oval (with spiral)
GF-UCT180	SD-210U-25, SD-240U-25	SD-221U-25	SD-230U-20

Appendix B: Inspection of the endoscope after cleaning, disinfection or sterilization in accordance with IEC 60601-2-37

After cleaning, disinfection or sterilization this instrument, check the parts or accessories that can be contaminated through contact with the patient, with body fluids, or with expired gases according to the “Method of inspection” listed below.

Inspection of the endoscope after cleaning, disinfection or sterilization

Timing of inspection	Pertinent parts, components or functions	Method of inspection
After precleaning	Waterproof	See section 7.4, “Leakage testing” on page 108.
After cleaning, disinfection or sterilization	Inspection of the endoscope	See “Inspection of the endoscope” in Section 3.2, “Inspection of the endoscope”, on page 30.
	Bending mechanisms	See “Inspection of the bending mechanisms” in Section 3.2, “Inspection of the endoscope”, on page 31.
	Forceps elevator mechanism	See “Inspection of the forceps elevator mechanism” in Section 3.2, “Inspection of the endoscope”, on page 33.
	Air/water valve	See “Inspection of the air/water and suction valves” in Section 3.3, “Preparation and inspection of accessories”, on page 34.
	Suction valve	See “Inspection of the air/water and suction valves” in Section 3.3, “Preparation and inspection of accessories”, on page 34.
	Biopsy valve	See “Inspection of the biopsy valve” in Section 3.3, “Preparation and inspection of accessories”, on page 36.
	Mouthpiece	See “Inspection of the mouthpiece” in Section 3.3, “Preparation and inspection of accessories”, on page 37.
	Attaching the suction valve	See “Attaching the suction valve” in Section 3.4, “Attaching accessories to the endoscope”, on page 38.
	Attaching the air/water valve	See “Attaching the air/water valve” in Section 3.4, “Attaching accessories to the endoscope”, on page 39.
	Attaching the biopsy valve	See “Attaching the biopsy valve” in Section 3.4, “Attaching accessories to the endoscope”, on page 39.
	Connection of the suction tube	See “Connection of the endoscope and ancillary equipment” in Section 3.5, “Inspection and connection of ancillary equipment”, on page 43.

Timing of inspection	Pertinent parts, components or functions	Method of inspection
After cleaning, disinfection or sterilization	Connection of the water container	See “Connection of the endoscope and ancillary equipment” in Section 3.5, “Inspection and connection of ancillary equipment”, on page 43.
	Connection of the videoscope cable	See “Connection of the endoscope and ancillary equipment” in Section 3.5, “Inspection and connection of ancillary equipment”, on page 43.
	Connection of the ultrasonic cable	See “Connection of the endoscope and ultrasonic cable” in Section 3.5, “Inspection and connection of ancillary equipment”, on page 45.
	Endoscopic image	See “Inspection of the endoscopic image” in Section 3.6, “Inspection of the endoscopic system”, on page 46.
	Remote switches	See “Inspection of the remote switches” in Section 3.6, “Inspection of the endoscopic system”, on page 47.
	Air feeding function	See “Inspection of the air-feeding function” in Section 3.6, “Inspection of the endoscopic system”, on page 47.
	Objective lens cleaning function	See “Inspection of the objective lens cleaning function” in Section 3.6, “Inspection of the endoscopic system”, on page 48.
	Water feeding function into the balloon	See “Inspection of the water feeding function into the balloon” in Section 3.6, “Inspection of the endoscopic system”, on page 48.
	Suction function	See “Inspection of the suction function” in Section 3.6, “Inspection of the endoscopic system”, on page 49.
	Aspiration from the balloon	See “Inspection of aspiration from the balloon water suction port” in Section 3.6, “Inspection of the endoscopic system”, on page 49.
	Instrument channel and forceps elevator	See “Inspection of the instrument channel and forceps elevator” in Section 3.6, “Inspection of the endoscopic system”, on page 50.
	Ultrasound image	See “Inspection of the ultrasound image with the Olympus universal endoscopic ultrasound center EU-ME1” and “Inspection of the ultrasound image with the ALOKA diagnostic ultrasound system” in Section 3.6, “Inspection of the endoscopic system”, on page 50 and 52.
	Balloon	See Section 3.7, “Preparation and inspection of the balloon” on page 52.

Appendix C: EMC Information

❍ Guidance and manufacturer's declaration — Electromagnetic emissions

This model is intended for use in the electromagnetic environment specified below. The customer or the user of this model should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — Guidance
RF emissions CISPR 11	Group 1	This instrument uses RF (Radio Frequency) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated emissions CISPR 11	Class B	This instrument's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Main terminal conducted emissions CISPR 11		
Harmonic emissions IEC 61000-3-2	Class A	This instrument's harmonic emissions are low and are not likely to cause any problem in the typical commercial power supply connected to this instrument.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	This instrument stabilizes its own radio variability and has no effect such as flicker in lighting apparatus.

Guidance and manufacturer's declaration — Electromagnetic immunity

This model is intended for use in the electromagnetic environment specified below. The customer or the user of this model should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±2, ±4, ±6 kV Air: ±2, ±4, ±8 kV	Same as left	Floors should be made of wood, concrete, or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Same as left	Mains power quality should be that of a typical commercial (original condition feeding the facilities) or hospital environment.
Surge IEC 61000-4-5	Differential mode: ±0.5, ±1 kV Common mode: ±0.5, ±1, ±2 kV	Same as left	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle	Same as left	Mains power quality should be that of a typical commercial or hospital environment. If the user of this instrument requires continued operation during power mains interruptions, it is recommended that this instrument be powered from an uninterruptible power supply or a battery.
	40% U_T (60% dip in U_T) for 5 cycle		
	70% U_T (30% dip in U_T) for 25 cycle		
	< 5% U_T (> 95% dip in U_T) for 5 seconds		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.
Definition:	U_T is the a.c. mains voltage prior to application of the test level.		

Guidance and manufacturer's declaration — Electromagnetic immunity

This model is intended for use in the electromagnetic environment specified below. The customer or the user of this model should assure that it is used in such an environment.

Portable and mobile RF communications equipment should be used no closer to any part of this model, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — Guidance
Conducted RF IEC 61000-4-6	3 Vrms (150 kHz – 80 MHz)	3 V (V_1)	Recommended separation distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m (80 MHz – 2.5 GHz)	3 V/m (E_1)	Recommended separation distance $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz – 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz – 2.5 GHz
Definition:	Where "P" is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m).		

NOTE

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- This instrument complies with the requirements of IEC 60601-1-2: 2007. However, under electromagnetic environment that exceeds its noise level, electromagnetic interference may occur on this instrument.
- Electromagnetic interference may occur in the vicinity of high-frequency electrosurgical equipment and/or other equipment marked with the following symbol:

NOTE

- Field strength from fixed RF transmitters as determined by an electromagnetic site survey[a)] should be less than the compliance level in each frequency range[b)].

  a) Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this model is used exceeds the applicable RF compliance level above, this model should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this model.

  b) Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

❍ Recommended separation distances between portable and mobile RF communications equipment and this model

This model is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this model can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this model as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter P (W)	Separation distance according to frequency of transmitter (m) (calculated as V_1=3 and E_1=3)		
	150 kHz – 80 MHz	80 MHz – 800 MHz	800 MHz – 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
Others:	For transmitters rated at a maximum output power not listed above, the recommended separation distance ‘d’ in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where ‘p’ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.		

NOTE

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix D: Acoustic Output Information in Accordance with the FDA Guidance: "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers"

Symbol key

MI	Mechanical Index
TIS_{scan}	Soft Tissue Thermal Index in an auto-scanning mode
$TIS_{non\text{-}scan}$	Soft Tissue Thermal Index in a non-autoscanning mode
TIB	Bone Thermal Index
TIC	Cranial Thermal Index
TI type	The applicable thermal index type
TI value	The thermal index value
A_{aprt}	Area of the active aperture (square centimeters)
$p_{r.3}$	Derated peak rarefactional pressure associated with the transmit pattern giving rise to the value reported under MI (megapascals)
W_0	Ultrasonic power except for TIS_{scan}, in which case it is the ultrasonic power passing through a one centimeter window (milliwatts)
$W_{.3}$ (Z1)	Derated ultrasonic power at axial distance z_1 (milliwatts)
$I_{TA.3}$ (Z1)	Derated spatial peak, temporal average intensity at axial distance z_1 (milliwatts per square centimeter)
z_1	Axial distance corresponding to the location of max [min ($W_{.3}$ (Z), $I_{TA.3}$ (Z) × 1 cm^2)] where $Z \geq Z_{bp}$ (centimeters)
z_{bp}	$1.69\sqrt{A_{aprt}}$ (centimeters)
z_{sp}	For MI, the axial distance at which $_{Pr.3}$ is measured for TIB, the axial distance at which TIB is a global maximum (i.e., $z_{sp} = z_{B.3}$) (centimeters)
$z@PII._{3max}$	Axial distance corresponding to the maximum of the derated spatial-peak pulse intensity integral (megapascals)

d_{eq} (Z_{sp})	Equivalent beam diameter as a function of axial distance z, and equal to $[(4/\pi)(W_0/I_{TA}(z))]^{0.5}$, where $I_{TA}(z)$ is the temporal-average intensity as a function of z (centimeters)
f_c	Center frequency (MHz). For MI, f_c is the center frequency associated with the transmit pattern giving rise to the global maximum reported value of MI. For TI, for combined modes involving transmit patterns of unequal center frequency, f_c is defined as the overall ranges of center frequencies of the respective transmit patterns
Dim. of A_{aprt}	Active aperture dimensions for azimuthal (x) and elevational (y) planes (centimeters)
PD	Pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of MI
PRF	Pulse repetition frequency associated with the transmit pattern giving rise to the reported value of MI (Hz)
p_r@PII_{max}	Peak rarefactional pressure at the point where the free-field, spatial-peak pulse intensely integral is a maximum (megapascals)
d_{eq}@PII_{max}	Equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum (centimeters)
FL	Focal length, or azimuthal (x) and elevational (y) lengths, if different (centimeters)
$I_{PA.3}$@MI_{max}	Derated pulse-average intensity at the point of global maximum reported MI (watts per square centimeter)
$I_{SPTA.3}$	Derated spatial peak temporal average intensity (milliwatts per square centimeter)
Derated I_{SPTA}	Derated spatial peak temporal average intensity (milliwatts per square centimeter)
PII	Pulse intensely integral

Acoustic output table with ALOKA diagnostic ultrasound system

❍ Acoustic output table for default settings when combined with SSD-α10

Transducer Model: **GF-UCT180**

Acoustic Output			*MI*	*TIS*	*TIB*	*TIC*
Maximum Value			0.36	0.11	0.21	0.18
Operating mode			Mflow	B/Bflow	PWD	B/Bflow
Operator Controls	DVA%	(%)	70	70	48	70
	Function		Off	Off	Off	Off
	B/W Frequency Select	(MHz)	n/a	7.5 MHz	n/a	7.5 MHz
	B/W Focus		n/a	F9	n/a	F9
	B/W-Range	(cm)	12.0	12.0	n/a	12.0
	B/W Line Density		n/a	HIGH	n/a	HIGH
	B/W Scan Area	(%)	n/a	100	n/a	100
	Doppler Image Select		n/a	n/a	STD	n/a
	Doppler Frequency Select	(MHz)	n/a	n/a	6 MHz	n/a
	Doppler Focus		n/a	n/a	F12	n/a
	Doppler Velocity Range	(cm/sec)	n/a	n/a	39.8	n/a
	Color Image Select		STD	STD	n/a	STD
	Color Doppler Frequency Select	(MHz)	5 MHz	5 MHz	n/a	5 MHz
	Flow Focus		F13	F13	n/a	F13
	Color Velocity Range	(m/sec)	0.12	0.12	n/a	0.12
	Color Line Density		n/a	LOW	n/a	LOW
	Color Average		n/a	MID	n/a	MID
	Flow Filter		n/a	#4	n/a	#4
	Flow Scan Area	(%)	n/a	49	n/a	49
	Triplex Velocity Range		n/a	n/a	n/a	n/a

	$I_{SPTA.3}$	(mW/cm^2)	34	7.0	68	7.0

❍ Acoustic output table for track3 when combined with SSD-α10

Transducer Model: **GF-UCT180** Operating Mode: **PWD-mode**

Index label				*MI*	*TIS*			*TIB*	*TIC*
					TIS_{scan}	**$TIS_{non\text{-}scan}$**		**Non-scan**	
						A_{aprt}<=1	A_{aprt}>1		
Maximum Index Value				0.88	–	0.71	–	1.7	0.96
Assoc. Acoustic Param.	$p_{r.3}$		(MPa)	2.0					
	W_0		(mW)		–	20		24	26
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]		(mW)				–		
	z_1		(cm)				–		
	z_{bp}		(cm)				–		
	z_{sp}		(cm)					1.4	
	z@PII$_{.3max}$		(cm)	1.4					
	$d_{eq}(z_{sp})$		(cm)					0.19	
	f_c		(MHz)	5.3	–	7.4	–	5.3	5.3
	Dim of A_{aprt}	X	(cm)		–	0.74	–	0.74	0.74
		Y	(cm)		–	0.50	–	0.50	0.50
Other Info.	PD		(μsec)	0.47					
	PRF		(Hz)	5210					
	p_r @PII_{max}		(MPa)	2.5					
	d_{eq} @ PII_{max}		(cm)					0.18	
	Focal Length	FL_x	(cm)		–	4.3	–		4.3
		FL_y	(cm)		–	1.0	–		1.0
	$I_{pa.3}$ @MI_{max}		(W/cm^2)	209					
Operator Controls	DVA%		(%)	100	–	89	–	97	100
	Function			CHE B	–	eF ExPHD	–	eF ExPHD	eF ExPHD
	B/W Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	B/W Focus			n/a	n/a	n/a	n/a	n/a	n/a
	B/W-Range		(cm)	n/a	n/a	n/a	n/a	n/a	n/a
	B/W Line Density			n/a	n/a	n/a	n/a	n/a	n/a
	B/W Scan Area		(%)	n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Image Select			PENET	–	PENET	–	PENET	PENET
	Doppler Frequency Select		(MHz)	5 MHz	–	7.5 MHz	–	5 MHz	5 MHz
	Doppler Focus			F5	–	F15	–	F11	F16
	Doppler Velocity Range		(cm/sec)	19.9	–	36.2	–	76.0	39.8
	Color Image Select			n/a	n/a	n/a	n/a	n/a	n/a
	Color Doppler Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	Flow Focus			n/a	n/a	n/a	n/a	n/a	n/a
	Color Velocity Range		(m/sec)	n/a	n/a	n/a	n/a	n/a	n/a
	Color Line Density			n/a	n/a	n/a	n/a	n/a	n/a
	Color Average			n/a	n/a	n/a	n/a	n/a	n/a
	Flow Filter			n/a	n/a	n/a	n/a	n/a	n/a
	Flow Scan Area		(%)	n/a	n/a	n/a	n/a	n/a	n/a
	Triplex Velocity Range			n/a	n/a	n/a	n/a	n/a	n/a
Display TIS_{max}						0.71			
Display TIB_{max}								1.7	

Transducer Model: **GF-UCT180** Operating Mode: **Mflow-mode**

Index label				*MI*	*TIS*			*TIB*	*TIC*
					TIS_{scan}	**$TIS_{non-scan}$**		**Non-scan**	
						A_{aprt}<=1	A_{aprt}>1		
Maximum Index Value				0.88	–	0.76	–	1.7	0.89
Assoc. Acoustic param.	$p_{r.3}$		(MPa)	2.0					
	W		(mW)		–	22		22	24
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]		(mW)				–		
	z_1		(cm)				–		
	z_{bp}		(cm)				–		
	z_{sp}		(cm)					1.2	
	z@$PII_{.3max}$		(cm)	1.4					
	$d_{eq}(z_{sp})$		(cm)					0.19	
	f_c		(MHz)	5.3	–	7.4	–	5.1	5.3
	Dim of A_{aprt}	X	(cm)		–	0.74	–	0.74	0.74
		Y	(cm)		–	0.50	–	0.50	0.50
Other Info.	PD		(μsec)	0.47					
	PRF		(Hz)	5210					
	p_r @PII_{max}		(MPa)	2.5					
	d_{eq} @ PII_{max}		(cm)					0.18	
	Focal Length	FL_x	(cm)		–	4.6	–		4.3
		FL_y	(cm)		–	1.0	–		1.0
	$I_{pa.3}$ @MI_{max}		(W/cm^2)	209					
Operator Controls	DVA%		(%)	100	–	100	–	100	100
	Function			CHE B	–	eF ExPHD	–	Off	eF ExPHD
	B/W Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	B/W Focus			n/a	n/a	n/a	n/a	n/a	n/a
	B/W-Range		(cm)	4.0	–	2.0	–	2.0	2.0
	B/W Line Density			n/a	n/a	n/a	n/a	n/a	n/a
	B/W Scan Area		(%)	n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Image Select			n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Focus			n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Velocity Range		(cm/sec)	n/a	n/a	n/a	n/a	n/a	n/a
	Color Image Select			PENET	–	PENET	–	PENET	PENET
	Color Doppler Frequency Select		(MHz)	5 MHz	–	7.5 MHz	–	5 MHz	5 MHz
	Flow Focus			F5	–	F16	–	F9	F16
	Color Velocity Range		(m/sec)	0.20	–	0.80	–	0.61	0.94
	Color Line Density			n/a	n/a	n/a	n/a	n/a	n/a
	Color Average			n/a	n/a	n/a	n/a	n/a	n/a
	Flow Filter			n/a	n/a	n/a	n/a	n/a	n/a
	Flow Scan Area		(%)	n/a	n/a	n/a	n/a	n/a	n/a
	Triplex Velocity Range			n/a	n/a	n/a	n/a	n/a	n/a
Display TIS_{max}						0.76			
Display TIB_{max}								1.7	

❍ Acoustic measurement uncertainty

Quantity	Uncertainty (95% confidence)
W_0	12.22%
PII	25.62%
Pr	13.19%
F_c	2.39%

Acoustic output table when combined with Olympus universal endoscopic ultrasound center EU-ME1

❍ Acoustic output table

$I_{SPTA.3}$	62
TI type	TIS, TIB
TI value	0.83
MI	0.99
$I_{PA.3}$ @MI_{max}	377

❍ Global maximum derated I_{SPTA} and MI values when combined with the EU-ME1

Imaging mode	Derated I_{SPTA}	MI
B mode	15	0.99
Color flow mode	46	0.97
Power flow mode	62	0.94

❍ Acoustic measurement precision and uncertainty

Quantity	Uncertainty (%)
Pr	17
W_0	44
f_c	17
PII	41
MI	20
$I_{SPTA.3}$	48

Clinical measurement accuracy with ALOKA diagnostic ultrasound system

❍ When combined with SSD-α10

Measurement feature	General accuracy	Round-off accuracy	
Distance in B-mode	±3%	±0.01 cm	<10 cm distance
		±0.1 cm	>10 cm distance
Area by trace in B-mode	±6%	±0.01 cm^2	<100 cm^2 area
		±0.1 cm^2	>100 cm^2 area
Circumference by trace B-mode	±6%	±0.01 cm	<10 cm distance
		±0.1 cm	>10 cm distance
Area by ellipses in B-mode	±5%	±0.01 cm^2	<100 cm^2 area
		±0.1 cm^2	>100 cm^2 area
Volume in B-mode	±7%	±0.01 cm^3	<100 cm^3 area
Excrusion in M-mode	±3%	±0.01 cm	<10 cm distance
		±0.1 cm	>10 cm distance
Time interval in M-mode	±3%	±1 ms	<1000 ms time
		±0.1 s	>1000 ms time
Velocity in Doppler mode	±10%	±0.1 cm/sec	
Heart rate	±1BPM or ±5%	±1 beat per minute	

Clinical measurement accuracy when combined with Olympus universal endoscopic ultrasound center EU-ME1

Measurement Feature	Accuracy	Maximum measurement range
Length	±5%	20 – 40 mm
Direction	±5%	20 mm
Circumference	±10%	20 – 40 mm
Area	±10%	20 – 40 mm

Appendix E: Acoustic Output Information Accordance with IEC 60601-2-37

Acoustic output table with ALOKA diagnostic ultrasound system

The terms used in the acoustic output table are as follows:

α	Acoustic attenuation coefficient
A_{aprt}	–12 dB output beam area
$A_{eq(z)}$	Normalizing coefficient
D_{eq}	Equivalent aperture diameter
d_{-6}	Pulse beam width
d_{eq}	Equivalent beam diameter
f_{awf}	Acoustic working frequency
I_{pa}	Pulse-average intensity
$I_{pa,\alpha}$	Attenuated pulse-average intensity
I_{pi}	Pulse-intensity integral
$I_{pi,\alpha}$	Attenuated pulse-intensity integral
$I_{ta(z)}$	Temporal-average intensity
$I_{ta,\alpha(z)}$	Attenuated temporal-average intensity
$I_{zpta(z)}$	Spatial-peak temporal-average intensity
$I_{zpta,\alpha(z)}$	Attenuated spatial-peak temporal-average intensity
MI	Mechanical index
P	Output power
P_{α}	Attenuated output power
P_{I}	Bounded output power
p_{i}	Pulse pressure squared integral

p_r	Peak-rarefactional acoustic pressure
$p_{r,\alpha}$	Attenuated peak-rarefactional acoustic pressure
prr	Pulse repetition rate
TI	Thermal index
TIB	Bone thermal index
TIC	Cranial-bone thermal index
TIS	Soft-tissue thermal index
TIS_{scan}	Soft tissue thermal index in an auto-scanning mode
$TIS_{non-scan}$	Soft tissue thermal index in a non-autoscanning mode
t_d	Pulse duration
X, Y	–12 dB output beam dimensions
z	Distance from the source to a specified point
z_b	Depth for TIB
z_{bp}	Break-point depth
z_s	Depth for TIS
f_c	Center frequency (MHz). For MI, f_c is the center frequency associated with the transmit pattern giving rise to the global maximum reported value of MI. For TI, for combined modes involving transmit patterns of unequal center frequency, f_c is defined as the overall ranges of center frequencies of the respective transmit patterns
PII	Pulse intensely integral

Acoustic measurement uncertainty

Quantity	Uncertainty (95% confidence)
P	12.22%
PII	25.62%
P_r	13.19%
F_c	2.39%

❍ Acoustic output table when combined with SSD-α10

Transducer Model: **GF-UCT180** Operating Mode: **B-mode**

Table 201.103 – Acoustic output reporting table

Index label				*MI*	*TIS*			*TIB*	*TIC*
					Scan	**Non-scan**		**Non-scan**	
						A_{aprt}≤**1cm²**	A_{aprt}>**1cm²**		
Maximum Index Value				0.84	0.69	–	–	–	0.76
Associated acoustic parameters	$p_{r,\alpha}$		(MPa)	2.0					
	P		(mW)		27	–		–	20
	Min of [$P_\alpha(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				–		
	z_s		(cm)				–		
	z_{bp}		(cm)				–		
	z_b		(cm)					–	
	z at max. $I_{pi,\alpha}$		(cm)	1.2					
	$d_{eq}(z_b)$		(cm)					–	
	f_{awf}		(MHz)	5.4	5.3	–	–	–	4.4
	Dim of A_{aprt}	X	(cm)		1.2	–	–	–	0.72
		Y	(cm)		0.50	–	–	–	0.50
Other information	t_d		(μsec)	0.29					
	prr		(Hz)	6940					
	p_r at max. I_{pi}		(MPa)	2.3					
	d_{eq} at max. I_{pi}		(cm)					–	
	$I_{pa,\alpha}$ at max.MI		(W/cm²)	313					
	Focal Length	FL_x	(cm)		2.8	–	–		0.56
		FL_y	(cm)		1.0	–	–		1.2
Operating control conditions	DVA%		(%)	100	100	–	–	–	100
	Function			CHE A Penet	CHE B	–	–	–	CHE A Penet
	B/W Frequency Select		(MHz)	5.4 MHz	5.4 MHz	–	–	–	4.3 MHz
	B/W Focus			F4	F9	–	–	–	F2
	B/W-Range		(cm)	8.0	4.0	–	–	–	4.0
	B/W Line Density			HIGH	HIGH	–	–	–	HIGH
	B/W Scan Area		(%)	25	25	–	–	–	25
	Doppler Image Select			n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Focus			n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Velocity Range		(cm/sec)	n/a	n/a	n/a	n/a	n/a	n/a
	Color Image Select			n/a	n/a	n/a	n/a	n/a	n/a
	Color Doppler Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	Flow Focus			n/a	n/a	n/a	n/a	n/a	n/a
	Color Velocity Range		(m/sec)	n/a	n/a	n/a	n/a	n/a	n/a
	Color Line Density			n/a	n/a	n/a	n/a	n/a	n/a
	Color Average			n/a	n/a	n/a	n/a	n/a	n/a
	Flow Filter			n/a	n/a	n/a	n/a	n/a	n/a
	Flow Scan Area		(%)	n/a	n/a	n/a	n/a	n/a	n/a
	Triplex Velocity Range			n/a	n/a	n/a	n/a	n/a	n/a

NOTE1 Data should only be entered in one of the columns related to TIS.

NOTE2 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE3 If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE4 If the requirements of 201.12.4.2b are met, it is not required to enter any data in the columns related to MI.

NOTE5 Focal Length is a NOMINAL value.

Transducer Model: **GF-UCT180** Operating Mode: **B/M-mode**

Table 201.103 – Acoustic output reporting table

Index label				*MI*	*TIS*			*TIB*	*TIC*
					Scan	**Non-scan**		**Non-scan**	
						A_{aprt}≤**1cm²**	A_{aprt}>**1cm²**		
Maximum Index Value				0.84	0.45	–	–	0.096	0.56
Associated acoustic parameters	$p_{r,\alpha}$		(MPa)	2.0					
	P		(mW)		22	–		0.91	18
	Min of [$P_\alpha(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				–		
	z_s		(cm)				–		
	z_{bp}		(cm)				–		
	z_b		(cm)					0.51	
	z at max. $I_{pi,\alpha}$		(cm)	1.2					
	$d_{eq}(z_b)$		(cm)					0.18	
	f_{awf}		(MHz)	5.4	4.4	–	–	4.4	4.3
	Dim of A_{aprt}	X	(cm)		1.1	–	–	0.31	1.2
		Y	(cm)		0.50	–	–	0.50	0.50
Other information	t_d		(μsec)	0.29					
	prr		(Hz)	5510					
	p_r at max. I_{pi}		(MPa)	2.3					
	d_{eq} at max. I_{pi}		(cm)					0.17	
	$I_{pa,\alpha}$ at max.MI		(W/cm²)	313					
	Focal Length	FL_x	(cm)		2.3	–	–		4.3
		FL_y	(cm)		1.2	–	–		1.2
Operating control conditions	DVA%		(%)	100	100	–	–	99	99
	Function			CHE A Penet	CHE A Penet	–	–	CHE A Penet	CHE A Penet
	B/W Frequency Select		(MHz)	5.4 MHz	4.3 MHz	–	–	4.3 MHz	4.3 MHz
	B/W Focus			F4	F7	–	–	F12	F12
	B/W-Range		(cm)	4.0	4.0	–	–	4.0	4.0
	B/W Line Density			HIGH	HIGH	–	–	HIGH	HIGH
	B/W Scan Area		(%)	25	25	–	–	25	25
	Doppler Image Select			n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Focus			n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Velocity Range		(cm/sec)	n/a	n/a	n/a	n/a	n/a	n/a
	Color Image Select			n/a	n/a	n/a	n/a	n/a	n/a
	Color Doppler Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	Flow Focus			n/a	n/a	n/a	n/a	n/a	n/a
	Color Velocity Range		(m/sec)	n/a	n/a	n/a	n/a	n/a	n/a
	Color Line Density			n/a	n/a	n/a	n/a	n/a	n/a
	Color Average			n/a	n/a	n/a	n/a	n/a	n/a
	Flow Filter			n/a	n/a	n/a	n/a	n/a	n/a
	Flow Scan Area		(%)	n/a	n/a	n/a	n/a	n/a	n/a
	Triplex Velocity Range			n/a	n/a	n/a	n/a	n/a	n/a

NOTE1 Data should only be entered in one of the columns related to TIS.

NOTE2 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE3 If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE4 If the requirements of 201.12.4.2b are met, it is not required to enter any data in the columns related to MI.

NOTE5 Focal Length is a NOMINAL value.

Transducer Model: **GF-UCT180** Operating Mode: **M-mode**

Table 201.103 – Acoustic output reporting table

Index label				*MI*	*TIS*			*TIB*	*TIC*
					Scan	**Non-scan**		**Non-scan**	
						A_{aprt}≤**1cm²**	A_{aprt}>**1cm²**		
Maximum Index Value				0.84	–	0.074	–	0.30	0.13
Associated acoustic parameters	$p_{r,\alpha}$		(MPa)	2.0					
	P		(mW)		–	3.6		3.0	3.6
	Min of [$P_{\alpha}(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				–		
	z_s		(cm)				–		
	z_{bp}		(cm)				–		
	z_b		(cm)					1.2	
	z at max. $I_{pi,\alpha}$		(cm)	1.2					
	$d_{eq}(z_b)$		(cm)					0.16	
	f_{awf}		(MHz)	5.4	–	4.3	–	4.4	4.3
	Dim of A_{aprt}	X	(cm)		–	0.74	–	0.55	0.74
		Y	(cm)		–	0.50	–	0.50	0.50
Other information	t_d		(μsec)	0.29					
	prr		(Hz)	1000					
	p_r at max. I_{pi}		(MPa)	2.3					
	d_{eq} at max. I_{pi}		(cm)					0.15	
	$I_{pa,\alpha}$ at max.MI		(W/cm²)	313					
	Focal Length	FL_x	(cm)		–	4.8	–		4.8
		FL_y	(cm)		–	1.2	–		1.2
Operating control conditions	DVA%		(%)	100	–	100	–	100	100
	Function			CHE A Penet	–	CHE A Penet	–	CHE A Penet	CHE A Penet
	B/W Frequency Select		(MHz)	5.4 MHz	–	4.3 MHz	–	4.3 MHz	4.3 MHz
	B/W Focus			F4	–	F15	–	F5	F15
	B/W-Range		(cm)	4.0	–	4.0	–	4.0	4.0
	B/W Line Density			n/a	n/a	n/a	n/a	n/a	n/a
	B/W Scan Area		(%)	n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Image Select			n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Focus			n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Velocity Range		(cm/sec)	n/a	n/a	n/a	n/a	n/a	n/a
	Color Image Select			n/a	n/a	n/a	n/a	n/a	n/a
	Color Doppler Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	Flow Focus			n/a	n/a	n/a	n/a	n/a	n/a
	Color Velocity Range		(m/sec)	n/a	n/a	n/a	n/a	n/a	n/a
	Color Line Density			n/a	n/a	n/a	n/a	n/a	n/a
	Color Average			n/a	n/a	n/a	n/a	n/a	n/a
	Flow Filter			n/a	n/a	n/a	n/a	n/a	n/a
	Flow Scan Area		(%)	n/a	n/a	n/a	n/a	n/a	n/a
	Triplex Velocity Range			n/a	n/a	n/a	n/a	n/a	n/a

NOTE1 Data should only be entered in one of the columns related to TIS.

NOTE2 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE3 If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE4 If the requirements of 201.12.4.2b are met, it is not required to enter any data in the columns related to MI.

NOTE5 Focal Length is a NOMINAL value.

Transducer Model: **GF-UCT180** Operating Mode: **PWD-mode**

Table 201.103 – Acoustic output reporting table

Index label				*MI*	*TIS*			*TIB*	*TIC*
					Scan	**Non-scan**		**Non-scan**	
						A_{aprt}≤**1cm²**	A_{aprt}>**1cm²**		
Maximum Index Value				0.88	–	0.62	–	1.7	0.93
Associated acoustic parameters	$p_{r,\alpha}$		(MPa)	2.0					
	P		(mW)		–	17		22	14
	Min of [$P_{\alpha}(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				–		
	z_s		(cm)				–		
	z_{bp}		(cm)				–		
	z_b		(cm)					1.2	
	z at max. $I_{pi,\alpha}$		(cm)	1.4					
	$d_{eq}(z_b)$		(cm)					0.19	
	f_{awf}		(MHz)	5.3	–	7.5	–	5.1	5.2
	Dim of A_{aprt}	X	(cm)		–	0.74	–	0.74	0.22
		Y	(cm)		–	0.50	–	0.50	0.50
Other information	t_d		(μsec)	0.47					
	prr		(Hz)	5210					
	p_r at max. I_{pi}		(MPa)	2.5					
	d_{eq} at max. I_{pi}		(cm)					0.18	
	$I_{pa,\alpha}$ at max.MI		(W/cm²)	209					
	Focal Length	FL_x	(cm)		–	3.4	–		0.27
		FL_y	(cm)		–	1.0	–		0.84
Operating control conditions	DVA%		(%)	100	–	100	–	100	97
	Function			CHE B	–	Off	–	Off	CHE A Std
	B/W Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	B/W Focus			n/a	n/a	n/a	n/a	n/a	n/a
	B/W-Range		(cm)	n/a	n/a	n/a	n/a	n/a	n/a
	B/W Line Density			n/a	n/a	n/a	n/a	n/a	n/a
	B/W Scan Area		(%)	n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Image Select			PENET	–	PENET	–	PENET	STD
	Doppler Frequency Select		(MHz)	5 MHz	–	7.5 MHz	–	5 MHz	5 MHz
	Doppler Focus			F5	–	F11	–	F9	F1
	Doppler Velocity Range		(cm/sec)	39.8	–	53.1	–	61.3	114
	Color Image Select			n/a	n/a	n/a	n/a	n/a	n/a
	Color Doppler Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	Flow Focus			n/a	n/a	n/a	n/a	n/a	n/a
	Color Velocity Range		(m/sec)	n/a	n/a	n/a	n/a	n/a	n/a
	Color Line Density			n/a	n/a	n/a	n/a	n/a	n/a
	Color Average			n/a	n/a	n/a	n/a	n/a	n/a
	Flow Filter			n/a	n/a	n/a	n/a	n/a	n/a
	Flow Scan Area		(%)	n/a	n/a	n/a	n/a	n/a	n/a
	Triplex Velocity Range			n/a	n/a	n/a	n/a	n/a	n/a

NOTE1 Data should only be entered in one of the columns related to TIS.

NOTE2 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE3 If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE4 If the requirements of 201.12.4.2b are met, it is not required to enter any data in the columns related to MI.

NOTE5 Focal Length is a NOMINAL value.

Transducer Model: **GF-UCT180** Operating Mode: **Mflow-mode**

Table 201.103 – Acoustic output reporting table

Index label				*MI*	*TIS*			*TIB*	*TIC*
					Scan	**Non-scan**		**Non-scan**	
						A_{aprt}≤**1cm²**	A_{aprt}>**1cm²**		
Maximum Index Value				0.88	–	0.76	–	1.7	0.89
Associated acoustic parameters	$p_{r,\alpha}$		(MPa)	2.0					
	P		(mW)		–	22		22	24
	Min of [$P_{\alpha}(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				–		
	z_s		(cm)				–		
	z_{bp}		(cm)				–		
	z_b		(cm)					1.2	
	z at max. $I_{pi,\alpha}$		(cm)	1.4					
	$d_{eq}(z_b)$		(cm)					0.19	
	f_{awf}		(MHz)	5.3	–	7.4	–	5.1	5.3
	Dim of A_{aprt}	X	(cm)		–	0.74	–	0.74	0.74
		Y	(cm)		–	0.50	–	0.50	0.50
Other information	t_d		(μsec)	0.47					
	prr		(Hz)	5210					
	p_r at max. I_{pi}		(MPa)	2.5					
	d_{eq} at max. I_{pi}		(cm)					0.18	
	$I_{pa,\alpha}$ at max.MI		(W/cm²)	209					
	Focal Length	FL_x	(cm)		–	4.6	–		4.3
		FL_y	(cm)		–	1.0	–		1.0
Operating control conditions	DVA%		(%)	100	–	100	–	100	100
	Function			CHE B	–	eF EPHD	–	Off	eF EPHD
	B/W Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	B/W Focus			n/a	n/a	n/a	n/a	n/a	n/a
	B/W-Range		(cm)	4.0	–	2.0	–	2.0	2.0
	B/W Line Density			n/a	n/a	n/a	n/a	n/a	n/a
	B/W Scan Area		(%)	n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Image Select			n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Focus			n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Velocity Range		(cm/sec)	n/a	n/a	n/a	n/a	n/a	n/a
	Color Image Select			PENET	–	PENET	–	PENET	PENET
	Color Doppler Frequency Select		(MHz)	5 MHz	–	7.5 MHz	–	5 MHz	5 MHz
	Flow Focus			F5	–	F16	–	F9	F16
	Color Velocity Range		(m/sec)	0.40	–	0.80	–	0.61	0.94
	Color Line Density			n/a	n/a	n/a	n/a	n/a	n/a
	Color Average			n/a	n/a	n/a	n/a	n/a	n/a
	Flow Filter			n/a	n/a	n/a	n/a	n/a	n/a
	Flow Scan Area		(%)	n/a	n/a	n/a	n/a	n/a	n/a
	Triplex Velocity Range			n/a	n/a	n/a	n/a	n/a	n/a

NOTE1 Data should only be entered in one of the columns related to TIS.

NOTE2 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE3 If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE4 If the requirements of 201.12.4.2b are met, it is not required to enter any data in the columns related to MI.

NOTE5 Focal Length is a NOMINAL value.

Transducer Model: **GF-UCT180** Operating Mode: **B/PWD-mode**

Table 201.103 – Acoustic output reporting table

Index label				*MI*	*TIS*			*TIB*	*TIC*
					Scan	**Non-scan**		**Non-scan**	
						A_{aprt}≤**1cm²**	A_{aprt}>**1cm²**		
Maximum Index Value				0.88	–	0.50	–	1.6	0.95
Associated acoustic parameters	$p_{r,\alpha}$		(MPa)	2.0					
	P		(mW)		–	14		15	16
	Min of [$P_{\alpha}(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				–		
	z_s		(cm)				–		
	z_{bp}		(cm)				–		
	z_b		(cm)					0.37	
	z at max. $I_{pi,\alpha}$		(cm)	1.4					
	$d_{eq}(z_b)$		(cm)					0.18	
	f_{awf}		(MHz)	5.3	–	7.5	–	5.3	4.3, 5.2
	Dim of A_{aprt}	X	(cm)		–	0.74	–	0.31	0.22
		Y	(cm)		–	0.50	–	0.50	0.50
Other information	t_d		(μsec)	0.47					
	prr		(Hz)	6640					
	p_r at max. I_{pi}		(MPa)	2.5					
	d_{eq} at max. I_{pi}		(cm)					0.16	
	$I_{pa,\alpha}$ at max.MI		(W/cm²)	209					
	Focal Length	FL_x	(cm)		–	2.7	–		0.27
		FL_y	(cm)		–	1.0	–		0.84
Operating control conditions	DVA%		(%)	100	–	100	–	92	100
	Function			CHE B	–	Off	–	CHE A Std	CHE A Std
	B/W Frequency Select		(MHz)	4.7 MHz	–	5 MHz	–	4.7 MHz	4.3 MHz
	B/W Focus			F5	–	F16	–	F2	F12
	B/W-Range		(cm)	4.0	–	4.0	–	12.0	4.0
	B/W Line Density			HIGH	–	HIGH	–	HIGH	HIGH
	B/W Scan Area		(%)	25	–	25	–	25	25
	Doppler Image Select			PENET	–	PENET	–	STD	STD
	Doppler Frequency Select		(MHz)	5 MHz	–	7.5 MHz	–	5 MHz	5 MHz
	Doppler Focus			F5	–	F8	–	F2	F1
	Doppler Velocity Range		(cm/sec)	53.1	–	39.8	–	79.7	133
	Color Image Select			n/a	n/a	n/a	n/a	n/a	n/a
	Color Doppler Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	Flow Focus			n/a	n/a	n/a	n/a	n/a	n/a
	Color Velocity Range		(m/sec)	n/a	n/a	n/a	n/a	n/a	n/a
	Color Line Density			n/a	n/a	n/a	n/a	n/a	n/a
	Color Average			n/a	n/a	n/a	n/a	n/a	n/a
	Flow Filter			n/a	n/a	n/a	n/a	n/a	n/a
	Flow Scan Area		(%)	n/a	n/a	n/a	n/a	n/a	n/a
	Triplex Velocity Range			n/a	n/a	n/a	n/a	n/a	n/a

NOTE1 Data should only be entered in one of the columns related to TIS.

NOTE2 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE3 If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE4 If the requirements of 201.12.4.2b are met, it is not required to enter any data in the columns related to MI.

NOTE5 Focal Length is a NOMINAL value.

Transducer Model: **GF-UCT180** Operating Mode: **B/Bflow-mode**

Table 201.103 – Acoustic output reporting table

Index label				*MI*	*TIS*			*TIB*	*TIC*
					Scan	**Non-scan**		**Non-scan**	
						A_{aprt}≤**1cm²**	A_{aprt}>**1cm²**		
Maximum Index Value				0.88	0.91	–	–	–	0.82
Associated acoustic parameters	$p_{r,\alpha}$		(MPa)	2.0					
	P		(mW)		26	–		–	27
	Min of [$P_{\alpha}(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				–		
	z_s		(cm)				–		
	z_{bp}		(cm)				–		
	z_b		(cm)					–	
	z at max. $I_{pi,\alpha}$		(cm)	1.4					
	$d_{eq}(z_b)$		(cm)					–	
	f_{awf}		(MHz)	5.3	5.5, 7.5	–	–	–	5.1, 5.5
	Dim of A_{aprt}	X	(cm)		1.1	–	–	–	1.1
		Y	(cm)		0.50	–	–	–	0.50
Other information	t_d		(μsec)	0.47					
	prr		(Hz)	8730					
	p_r at max. I_{pi}		(MPa)	2.5					
	d_{eq} at max. I_{pi}		(cm)					–	
	$I_{pa,\alpha}$ at max.MI		(W/cm²)	209					
	Focal Length	FL_x	(cm)		2.7	–	–		3.8
		FL_y	(cm)		1.0	–	–		0.84
Operating control conditions	DVA%		(%)	100	100	–	–	–	100
	Function			CHE B	Off	–	–	–	Off
	B/W Frequency Select		(MHz)	4.7 MHz	5 MHz	–	–	–	5 MHz
	B/W Focus			F5	F15	–	–	–	F14
	B/W-Range		(cm)	4.0	4.0	–	–	–	4.0
	B/W Line Density			HIGH	HIGH	–	–	–	HIGH
	B/W Scan Area		(%)	25	25	–	–	–	25
	Doppler Image Select			n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Focus			n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Velocity Range		(cm/sec)	n/a	n/a	n/a	n/a	n/a	n/a
	Color Image Select			PENET	PENET	–	–	–	PENET
	Color Doppler Frequency Select		(MHz)	5 MHz	7.5 MHz	–	–	–	5 MHz
	Flow Focus			F5	F8	–	–	–	F16
	Color Velocity Range		(m/sec)	0.76	0.50	–	–	–	0.61
	Color Line Density			LOW	LOW	–	–	–	LOW
	Color Average			HIGH	HIGH	–	–	–	HIGH
	Flow Filter			#4	#4	–	–	–	#4
	Flow Scan Area		(%)	20	20	–	–	–	20
	Triplex Velocity Range			n/a	n/a	n/a	n/a	n/a	n/a

NOTE1 Data should only be entered in one of the columns related to TIS.

NOTE2 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE3 If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE4 If the requirements of 201.12.4.2b are met, it is not required to enter any data in the columns related to MI.

NOTE5 Focal Length is a NOMINAL value.

Transducer Model: **GF-UCT180** Operating Mode: **Power flow-mode**

Table 201.103 – Acoustic output reporting table

Index label				*MI*	*TIS*			*TIB*	*TIC*
					Scan	**Non-scan**		**Non-scan**	
						$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
Maximum Index Value				0.88	0.91	–	–	–	0.82
Associated acoustic parameters	$p_{r,\alpha}$		(MPa)	2.0					
	P		(mW)		26	–		–	27
	Min of [$P_\alpha(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				–		
	z_s		(cm)				–		
	z_{bp}		(cm)				–		
	z_b		(cm)					–	
	z at max. $I_{pi,\alpha}$		(cm)	1.4					
	$d_{eq}(z_b)$		(cm)					–	
	f_{awf}		(MHz)	5.3	5.5, 7.5	–	–	–	5.1, 5.5
	Dim of A_{aprt}	X	(cm)		1.1	–	–	–	1.1
		Y	(cm)		0.50	–	–	–	0.50
Other information	t_d		(μsec)	0.47					
	prr		(Hz)	8730					
	p_r at max. I_{pi}		(MPa)	2.5					
	d_{eq} at max. I_{pi}		(cm)					–	
	$I_{pa,\alpha}$ at max.MI		(W/cm^2)	209					
	Focal Length	FL_x	(cm)		2.7	–	–		3.8
		FL_y	(cm)		1.0	–	–		0.84
Operating control conditions	DVA%		(%)	100	100	–	–	–	100
	Function			CHE B	Off	–	–	–	Off
	B/W Frequency Select		(MHz)	4.7 MHz	5 MHz	–	–	–	5 MHz
	B/W Focus			F5	F15	–	–	–	F14
	B/W-Range		(cm)	4.0	4.0	–	–	–	4.0
	B/W Line Density			HIGH	HIGH	–	–	–	HIGH
	B/W Scan Area		(%)	25	25	–	–	–	25
	Doppler Image Select			n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Frequency Select		(MHz)	n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Focus			n/a	n/a	n/a	n/a	n/a	n/a
	Doppler Velocity Range		(cm/sec)	n/a	n/a	n/a	n/a	n/a	n/a
	Color Image Select			PENET	PENET	–	–	–	PENET
	Color Doppler Frequency Select		(MHz)	5 MHz	7.5 MHz	–	–	–	5 MHz
	Flow Focus			F5	F8	–	–	–	F16
	Color Velocity Range		(m/sec)	0.76	0.50	–	–	–	0.61
	Color Line Density			LOW	LOW	–	–	–	LOW
	Color Average			HIGH	HIGH	–	–	–	HIGH
	Flow Filter			#4	#4	–	–	–	#4
	Flow Scan Area		(%)	20	20	–	–	–	20
	Triplex Velocity Range			n/a	n/a	n/a	n/a	n/a	n/a

NOTE1 Data should only be entered in one of the columns related to TIS.

NOTE2 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE3 If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE4 If the requirements of 201.12.4.2b are met, it is not required to enter any data in the columns related to MI.

NOTE5 Focal Length is a NOMINAL value.

Transducer Model: **GF-UCT180** Operating Mode: **B/Bflow/D-mode**

Table 101 – Acoustic output reporting table

Index label				*MI*	*TIS*			*TIB*	*TIC*
					Scan	**Non-scan**		**Non-scan**	
						A_{aprt}≤**1cm²**	A_{aprt}>**1cm²**		
Maximum Index Value				0.88	–	0.50	–	1.6	0.90
Associated acoustic parameters	$p_{r,\alpha}$		(MPa)	2.0					
	P		(mW)		–	14		15	14
	Min of [$P_{\alpha}(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				–		
	z_s		(cm)				–		
	z_{bp}		(cm)				–		
	z_b		(cm)					0.37	
	z at max. $I_{pi,\alpha}$		(cm)	1.4					
	$d_{eq}(z_b)$		(cm)					0.18	
	f_{awf}		(MHz)	5.3	–	7.5	–	5.3	5.2, 5.4
	Dim of A_{aprt}	X	(cm)		–	0.74	–	0.31	0.22
		Y	(cm)		–	0.50	–	0.50	0.50
Other information	t_d		(μsec)	0.47					
	prr		(Hz)	11800					
	p_r at max. I_{pi}		(MPa)	2.5					
	d_{eq} at max. I_{pi}		(cm)					0.16	
	$I_{pa,\alpha}$ at max.MI		(W/cm²)	209					
	Focal Length	FL_x	(cm)		–	2.7	–		0.27
		FL_y	(cm)		–	1.0	–		0.84
Operating control conditions	DVA%		(%)	100	–	100	–	92	100
	Function			CHE B	–	Off	–	CHE A Std	CHE A Std
	B/W Frequency Select		(MHz)	4.7 MHz	–	5 MHz	–	5.4 MHz	4.3 MHz
	B/W Focus			F5	–	F16	–	F1	F15
	B/W-Range		(cm)	4.0	–	4.0	–	10.0	4.0
	B/W Line Density			HIGH	–	HIGH	–	HIGH	HIGH
	B/W Scan Area		(%)	25	–	25	–	25	25
	Doppler Image Select			PENET	–	PENET	–	STD	STD
	Doppler Frequency Select		(MHz)	5 MHz	–	7.5 MHz	–	5 MHz	5 MHz
	Doppler Focus			F2	–	F8	–	F2	F1
	Doppler Velocity Range		(cm/sec)	106	–	53.1	–	93.8	133
	Color Image Select			PENET	–	PENET	–	STD	STD
	Color Doppler Frequency Select		(MHz)	5 MHz	–	5 MHz	–	3.75 MHz	5 MHz
	Flow Focus			F5	–	F16	–	F16	F15
	Color Velocity Range		(m/sec)	0.33	–	0.25	–	0.33	0.33
	Color Line Density			LOW	–	LOW	–	LOW	LOW
	Color Average			HIGH	–	HIGH	–	HIGH	HIGH
	Flow Filter			#4	–	#4	–	#4	#4
	Flow Scan Area		(%)	20	–	20	–	20	20
	Triplex Velocity Range			HIGH	–	HIGH	–	HIGH	HIGH

NOTE1 Data should only be entered in one of the columns related to TIS.

NOTE2 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE3 If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE4 If the requirements of 201.12.4.2b are met, it is not required to enter any data in the columns related to MI.

NOTE5 Focal Length is a NOMINAL value.

Acoustic output table with Olympus universal endoscopic ultrasound center EU-ME1

GF-UCT180 will not exceed an MI of 1.0, or an $I_{SPTA.3}$ of 720 mW/cm^2 in any mode. In addition, GF-UCT180 will not exceed a TI of 1.0 in any mode.

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